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HEALTHCARE LAW PRACTICE GROUP NEWS REPORT

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HIPAA

CHANGES TO HIPAA PRIVACY RULE WILL REQUIRE COVERED ENTITIES AND BUSINESS ASSOCIATES TO PROVIDE ACCOUNTINGS OF DISCLOSURES AND ACCESS REPORTS OF PROTECTED HEALTH INFORMATION TO INDIVIDUALS

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I. Introduction

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) established national standards to protect the privacy and security of personal health information (“PHI”). In 2003, the HIPAA Privacy Rule was passed. It requires covered entities (“Covered Entities”) to make available to an individual, upon request, an accounting of certain disclosures of the individual’s PHI made during the six (6) years prior to the request. This rule applies to disclosures of both paper and electronic PHI, regardless of whether such information is in a designated record set (“DRS”).² It includes disclosures to and by Covered Entities’ business associates (“Business Associates”)³ with some exemptions.

In 2009, the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”) was passed. It provides, among other things, that an exemption to the HIPAA Privacy Rule for disclosures to carry out *treatment, payment and health care operations* no longer applies to disclosures through an electronic health record (“EHR”). The Department of Health and Human Services (“HHS”) has issued a notice of proposed rulemaking (“NPRM”)* to modify the HIPAA Privacy Rule with provisions from the HITECH Act.

The purpose of the proposed rule is to implement the statutory requirement under the HITECH Act to require Covered Entities and Business Associates to account for disclosures of PHI through an EHR. The current HIPAA Privacy Rule lists the exemptions (where disclosure is not required); the proposed rule will, instead, provide a list of required disclosures.

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II. What changes are proposed in the NPRM?

The NPRM was published on May 31, 2011 in the *Federal Register*. The comment period ended on August 1, 2011 with the Final Rule expected to be published by December 2011. The NPRM will revise the HIPAA Privacy Rule into two separate rights for individuals. The first is an individual's right to an accounting of disclosures (which continues to apply to both paper records of PHI and electronic PHI). The second is an individual's right to an access report, which includes electronic PHI accessed by both workforce members and persons outside the Covered Entity. The right to an access report is a new proposal under the NPRM, whereas the right to an accounting already exists. Both Covered Entities and Business Associates would now be required to account for disclosures of PHI in EHRs that are "part of a DRS for treatment, payment and health care operations", which were previously exempted from the rule.

As for the second right, the proposal includes expanding the accounting provision so that Covered Entities and now, Business Associates would be required to provide individuals with an "access report" that indicates who has accessed the individual's electronic PHI held by a Covered Entity or Business Associate.

This right is a new proposal and it assumes that Covered Entities and Business Associates can readily produce such reports. It would apply when any person accesses an electronic PHI in a DRS. The access report would identify the date, time and the name of the person (or name of the entity if the person's name is unavailable) who accessed the information. The Covered Entity would be required to permit the individual to narrow the request for an access report to a specific time frame or person. In addition, the access report must be in a format that is readable to all individuals.

Furthermore, entities would be required to inform individuals of their newly expanded rights. This would compel entities to update and revise their Notice of Privacy Practices. The disclosure period would be shortened from a six-(6) year period to a three-(3) year period to maintain the accounting for disclosures. However, other requirements to maintain documentation (such as policies and procedures) remains at six (6) years. Business Associates would be required to comply with accounting for disclosure requirements and create new electronic PHI access reports. These changes would likely go into effect beginning on January 1, 2013 and January 1, 2014, depending on when electronic DRS systems were acquired.

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III. What is the intent of the NPRM and what is the impact on you?

The overall intent of the NPRM is to include both Business Associates and Covered Entities to implement the HIPAA Privacy Rule as required under the HITECH Act.

The intent of the accounting of disclosures is to provide more detailed information (a “full accounting”) for certain disclosures that are most likely to impact an individual. The intent of the access report is to allow individuals to learn if specific persons have accessed their electronic DRS information.

The impact on Covered Entities and Business Associates appears understated in the NPRM. The NPRM, if finalized in its current form, will require entities to revise their current policies and procedures and update their EHR applications that are used to log and track these types of disclosures. Covered Entities and Business Associates would have to review their Agreements with one another to determine who is responsible for providing the accounting/access report to the individual—this responsibility is usually a negotiated term. It will likely greatly increase the cost of EHR systems to Covered Entities and Business Associates because it will require upgrades and revisions to how information is captured and reported. Another concern is that patient care time will be reduced because of the disruptions in work flow. Moreover and as mentioned above, Notices of Privacy Practices will have to be revised and distributed to all individuals within specified time frames. Finally, the health care industry is concerned because this proposed rule may have a chilling effect on the implementation of EHR systems, especially among small providers.

For more information or questions about your legal and compliance needs in connection with HIPAA, HITECH and any and all regulations and laws that may impact your business, please do not hesitate to contact our Health Care Law attorneys at Schenck, Price, Smith & King, LLP at 973-539-1000.

**There are other nuances included in this NPRM, but this article is only meant to provide a broad and general overview of some of the highlights of the proposed rule and is not meant to constitute legal advice.*

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¹Covered Entities are defined under HIPAA and the simple definition is an entity that is (a) a health care provider that conducts certain transactions in electronic form; (b) a health care clearinghouse; or (c) a health plan.

²A DRS is generally a group of records, including PHI, maintained by or for a health plan or health care provider, that is (i) the medical records and billing records about individuals maintained by or for a covered health care provider; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) used to make decisions about individuals.

³In general, a Business Associate is defined under HIPAA as a person/organization (other than a member of a covered entity's workforce) that performs certain functions on behalf of or to a covered entity that involve the use or disclosure of individually identifiable health information; for example, activities including claims processing, data analysis, utilization review, and billing. However, persons/organizations are not considered business associates if their functions do not involve the use or disclosure of PHI, and where any access to PHI by such persons would be incidental, if at all.