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The OCR Issues FAQs Regarding Family History Information Under the Privacy Rule

On January 13, 2009, the Department of Health and Human Services Office for Civil Rights (“OCR”) released a new series of answers to frequently asked questions (“FAQs”) to clarify the HIPAA Privacy Rule as it applies to family history information. The FAQs provide that, while covered entities are limited in the use and disclosure of protected health information (“PHI”), the patient is free to share the health information of his or her family members with their respective physicians in order to provide a complete medical history.

The FAQs indicate that such family history is only considered protected health information (“PHI”) for the patient in whose medical record the information is documented. The OCR clarifies that, “the individual (and not the family members included in the medical history) may exercise the rights under the HIPAA Privacy Rule to this information in the same fashion as any other information in the medical record, including the right of access, amendment, and the ability to authorize disclosure to others.”

The OCR also states that a healthcare provider is permitted under the Privacy Rule to disclose the PHI of an individual to another provider, without requiring the authorization of the individual, when the information is requested for the treatment of that individual’s family member. The example was given of a physician who may share information regarding an adverse reaction an individual had to anesthesia with the treating physician of the individual’s family member.

The FAQs reiterate that, while the Privacy Rule permits such disclosure, a covered healthcare provider is under no obligation to do so. In addition, an individual may request certain restrictions on the use or disclosure of his or her PHI for treatment purposes, although

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Contact Us

<http://www.kgrlaw.com>

mjc@kgrlaw.com

lmb@kgrlaw.com

the physician or health care provider is not required to agree to the request. However, the physician must abide by the restrictions if he or she agrees to the restriction.

As always, the covered physician or health care provider should disclose only the minimum necessary information required for the treatment of the individual or their family member.

For more information on the HIPAA Privacy Rules please contact Linda Batten at lmb@kgrlaw.com or Mark Colucci at mjc@kgrlaw.com.

WellPoint Sanctioned for Medicare Advantage and Prescription Drug Failures

Intermediate sanctions have been imposed on WellPoint, Inc. ("WellPoint") by the Center for Medicare and Medicaid Services ("CMS"). Effective January 12, 2009, WellPoint is suspended from enrolling new Medicare beneficiaries and marketing to such beneficiaries until CMS is satisfied that WellPoint has corrected the deficiencies giving rise to the sanctions and that they will not likely re-occur. CMS reserved the right to impose additional sanctions and or seek other remedies. WellPoint was informed of the suspension by letter dated January 12 from Abby L. Block, the Director of the Center for Drug and Health Plan Choice.

The sanctions were precipitated not only by enrollee complaints, but WellPoint's own self-disclosures. CMS characterized the WellPoint's deficiencies as "longstanding and persistent" failures that posed a "serious threat to the health and safety" of beneficiaries relating to the administration of Medicare Advantage Prescription Drug Plans ("MA-PD") and Prescription Drug Plans ("PDP"). Beneficiaries were allegedly overcharged and "denied access to critical medications" due to "pervasive" problems with the WellPoint information system. After several months of attempting to address the concerns, CMS stated that WellPoint had assured CMS the "problem was immediately and fully corrected."

Among the specific deficiencies outlined in the *CMS letter*, CMS accused WellPoint of:

- failing to promptly pay clean claims for non-contracted providers;
- charging premiums in excess of the maximum permitted;
- failure to timely process enrollment and disenrollment;
- failure to permit beneficiaries to pay full monthly premiums

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mjc@kgrlaw.com

lmb@kgrlaw.com

- through the Social Security Administration (SSA) premium withhold process; and
- failure to properly conduct CMS required enrollment and payment reconciliation.

WellPoint issued a statement on January 12, 2009, noting that it had action plans reviewed and approved by CMS to remediate its deficiencies, that it has been meeting with CMS on a regular basis regarding the remediation process, and that it was “surprised by this recent action.”

For more information please contact Mark Colucci at mjc@kgrlaw.com or Linda Batten at lmb@kgrlaw.com.

OIG Issues Opinion on Group Practice Investments

On December 29, the Department of Health and Human Services Office of the Inspector General (“OIG”) issued an advisory opinion on the likelihood that investments in a shared medical practice by 23 physicians and podiatrists would violate the Federal anti-kickback statute. The practice included urgent care consultation and clinical laboratory and radiology services and the investors practiced only part time at group locations with the exception of one licensed physician investor who owned a 1% interest but did not treat any patients at the practice. The practice was governed by a Board of Managers which also formulated business and clinical policies for the practice. Expenses and revenues were pooled throughout the practice rather than subdivisions of the practice. In office ancillary service revenue satisfied the requirements of section 1877(b)(2).

The OIG noted that the safe harbor for investments in group practices requires, among other things, that the equity interests in the group be held by practicing professionals in the group. The safe harbor was not met because “only” 99% of the equity interests satisfied this element. However, the OIG stated that it would not pursue administrative sanctions after looking at the “totality of the facts and circumstances.” The OIG noted that, except for the 1% interest, all equities in the practiced were owned by licensed physicians and podiatrists who treat patients at the practice.

Further, the OIG reasoned that the stakeholder’s 1% interest did “not post any appreciable additional risks to Federal programs or beneficiaries,” because the stakeholder’s returns were directly proportionally to his investment in the practice and he provided “substantial services integral to the Practice’s operation and administration, thus minimizing the risk that his small equity interest

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mjc@kgrlaw.com

lmb@kgrlaw.com

reflects referrals.” Therefore, while the OIG acknowledged that the proposed arrangements could potentially generate prohibited remuneration under the anti-kickback statute, it concluded it would not to pursue administrative sanctions.

For more information on the anti-kickback statute or the Stark laws, please contact Mark Colucci at mjc@kgrlaw.com or Linda Batten at lmb@kgrlaw.com.

Americans with Disabilities Act Expands Protections

The ADA Amendments Act of 2008, effective on January 1, 2009 (the “Amendment”), expanded the scope of the Americans with Disabilities Act (the “Act”) in a manner that some fear could result in an increase in employee lawsuits alleging discrimination under the Act, while making it more difficult to dispose of such cases prior to trial. Among the changes, the Amendment broadens the definition of the term “disability.”

The Amendment was largely aimed at reversing United States Supreme Court decisions narrowing the scope of the ADA. The Supreme Court has ruled that persons with serious disabilities that were controlled by medications or other mitigating measures did not qualify for protection under the ADA. It had also ruled that an impairment must prevent or severely restrict the individual from activities of central importance to most people’s lives. Other courts had also determined that persons with conditions that were episodic could only be considered disabled when the conditions were active.

Pursuant to the Amendment, a disability is now determined solely on the medical condition, without regard to the effectiveness of treatment or other mitigating measures (with an exception for poor vision rectified by eyeglasses). Also, an episodic illness is deemed a disability if it would substantially limit a major life activity when the condition is active. The Amendment did not alter the requirement that an impairment must substantially limit a major life activity, but did significantly expand the statutory list of what is considered a major life activity. Finally, the Amendment explicitly states the definition of disability is to be construed in favor of broad coverage of individuals.

The likely result of the Amendment will be an increase in claims by employees based on a disability. Given the construction in favor of broad coverage, employers will have a greater challenge successfully defending against such claims.

For more information regarding the ADA Amendments, please contact Mark Colucci at mjc@kgrlaw.com or Linda Batten at lmb@kgrlaw.com.