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OCR Guidance on Disclosures to Friends and Family

The Health and Human Services Office for Civil Rights (OCR) released new guidance this month regarding HIPAA and when and how providers may share a patient's health information with patient family and friends. The guidance was provided in a question and answer format with separate guidance issued for patients and for providers.

Generally, a provider may share information with family and friends when the patient has expressly authorized such disclosures. The OCR guidance also allows a provider to share information with family and friends if the patient has an opportunity to object and does not do so. For example, the provider may simply ask the patient if he/she minds if the provider discusses the patient's care in front of the family or friends. OCR's guidance also indicates that providers may decide from the circumstances, based on professional judgment, the patient does not object. Disclosures may be in person, or over the phone.

OCR's guidance addresses circumstances in which the patient is not present or is incapacitated. HIPAA has always allowed providers to use their professional judgment as to what is in the patient's best interest for disclosing information to the patient's family or friends, especially in emergency situations. The OCR guidance reinforces that understanding and adds that the provider may use professional judgment to decide if it is in the patient's best interest to allow friends or family to pick up prescriptions, medical supplies, X-rays, or other similar forms of patient health information.

OCR guidance describes different circumstances in which a provider may disclose to a patient's family or friends various patient health care and payment information, but also stresses that the provider should be reasonably sure that the patient has involved that individual in his/her care. In case of doubt, the provider should look to the urgency of the situation and the need to disclose patient

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information. If time and circumstances allow, it is always best to obtain the patient's consent for such disclosures. Providers should review their current policies and HIPAA programs to ensure that such policies are reflective of current HIPAA rules and guidelines. Such a review is important to ensure that the provider or facility is actually putting such policies into practice.

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

Patient Safety Inside and Outside of the Treatment Room

There have been several recent reports regarding patient risks while on the premises of a hospital or provider's office. For example in Los Angeles, a mentally disabled 76-year-old man in failing health disappeared from a city hospital. After hospital employees called the driver for the man, they then took him to the crowded hospital lobby and left him alone. In Brooklyn, a 49-year-old woman collapsed and died on the floor of a waiting room at a psychiatric hospital after waiting there nearly 24 hours for treatment.

On July 31, 2008, the Centers for Medicare & Medicaid Services (CMS) announced new Medicare and Medicaid payment and coverage policies to improve safety for hospitalized patients. The Inpatient Prospective Payment System (IPPS) FY 2009 final rule expands the list of selected hospital-acquired conditions (HACs) that will have Medicare payment implications beginning October 1, 2008. In addition, CMS has announced the initiation of three Medicare National Coverage Determinations (NCD) proceedings for "wrong surgery," a category of "never events" included in the National Quality Forum's (NQFs) list of Serious Reportable Adverse Events.

The following is a partial list of the current NQF "never events":

Surgical Events

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure on a patient
- Retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately post-operative death in a normal healthy patient

Product or Device Events

- Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- Patient death or serious disability associated with the use or function of a device in patient care in which the device is used

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or functions other than as intended

- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

Patient Protection Events

- Infant discharged to the wrong person
- Patient death or serious disability associated with patient disappearance for more than four hours
- Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility

Care Management Events

- Patient death or serious disability associated with a medication error
- Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products (transfusion of the wrong blood type)
- Maternal death or serious disability associated with labor or delivery on a low-risk pregnancy while being cared for in a healthcare facility
- Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- Death or serious disability (kernicterus) associated with failure to identify and treat jaundice in newborns
- Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- Patient death or serious disability due to spinal manipulative therapy

There are financial implications related to health care reimbursement as the health care industry focuses more and more on patient safety. Many commercial health care insurers are following Medicare's lead by enacting new payment policies based on patient safety initiatives. Patient treatment for conditions deemed preventable or resulting from "never events" may not be covered by Medicare, Medicaid, and even non-government payors. More than ever, hospitals and healthcare providers should evaluate their policies regarding patient safety both in and out of the treatment rooms. Formal policy development can assist providers in evaluating their risk areas, can establish better procedures for preventing and handling issues, and can provide added legal protection when such policies are actively followed.

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Department of Justice Gives More Protection to the Attorney- Client Privilege and Work Product Doctrine

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On August 28, the Department of Justice revised its guidelines for federal prosecutors charging corporations with fraud and other crimes. The revised document, Principles of Federal Prosecution of Business Organizations, is used by all federal prosecutors for guidance in investigating, charging and prosecuting corporate crimes. Corporations who are under investigation sometimes receive favorable settlements by cooperating with the federal investigation. However, investigators often required corporations to waive their attorney-client privilege and work product protections to receive such favorable terms.

Under the new guidelines, “[c]orporations that disclose relevant facts may receive due credit for cooperation, regardless of whether they waive attorney-client privilege or work product protection in the process.” Moreover, federal prosecutors are now forbidden from requiring corporations to disclose certain non-factual attorney-client privileged communication and work product, such as legal advice. The revised guidelines also prohibit federal prosecutors from considering whether the corporation has advanced attorney’s fees to employees, entered into a joint defense agreement, or disciplined or terminated employees when determining whether to give credit for cooperation.

The new policy impacts health care organizations that self-disclose wrongdoing to the Department of Justice. However, the guidelines are only binding on the Department of Justice, not the Department of Health and Human Services. Therefore, a health care organization may still be required to waive attorney-client privilege or work product when disclosing to the Office of Inspector General.

DOJ Press Release

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OIG Approves Administrative Services Arrangement

On September 26, the OIG approved a fee for service administrative services arrangement benefitting radiology and imaging centers. The “Requestor” proposed to organize and wholly own and manage a new entity (“Newco”). Newco proposed to process and submit insurance preauthorizations on behalf of radiology and imaging centers (the “Centers”) whenever a Center’s patient’s insurer required such a preauthorization (the “Services”). The Centers would pay Newco the same, fair market, “per service” fee for each preauthorization processed and submitted, without regard to whether the preauthorization was granted. Neither the Requestor nor Newco

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(nor their affiliates) would have any other direct or indirect financial relationship with any Center.

While noting that the safe harbor for personal services and management contracts could be applicable to the arrangement, the OIG stated that the safe harbor was not met. Specifically, the safe harbor requires aggregate compensation under such contracts be set in advance, and the payments under the Newco arrangement would be paid on a per service basis. Thus, the aggregate compensation would not be set in advance. However, the OIG did not consider the absence of the safe harbor to be fatal.

Instead, the OIG simply determined that the arrangement was “distinguishable from potentially problematic arrangements where administrative services are provided by, or on behalf of, a supplier, such as an imaging company or a manufacturer, to an existing or potential referral source. In those situations, there is a significant risk that at least one purpose of providing the services is to influence referrals to the party providing the services.” The distinction made by the OIG was based upon several factors, including the fact that the arrangement was not designed to promote particular services because Newco was not “a health care provider, practitioner, or supplier or in any way affiliated with the health care industry” and the services themselves were not in the nature of marketing. Moreover, the OIG noted that Newco would have no patient contact because all patient information was delivered by the Centers. “Newco’s Services do not involve coding, billing, or claims processing or review, which are activities that can, in some circumstances, generate Federal health care program business.”

The OIG opinion is a helpful guide for health care suppliers considering fee for service arrangements. Such arrangements are not a per se violation of the anti-kickback statute and the inability to meet a safe harbor is not necessarily prohibitive. However, in a final note, the OIG warned that such an arrangement could violate the anti-kickback statute if a Center or other third-party paid Newco to provide the Services for the benefit of a referral source.

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