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Compliance *Matters* ...

As everyone is working to grasp the full impact of the recently enacted health care reform legislation, the Patient Protection and Affordable Care Act, one thing is perfectly clear -- the Office of the Inspector General ("OIG") is well positioned with new tools, funding, and fraud fighting mechanisms to respond aggressively to fraud and abuse. Recent testimony by Lewis Morris, Chief Counsel to the Office of the Inspector General ("OIG"), sets the tone for what lies ahead and builds on the more than 30 years the OIG has spent protecting federal health care programs and its beneficiaries (http://www.oig.hhs.gov/testimony/docs/2010/morris_testimony61410.pdf). The OIG recognizes that the majority of health care providers are honest and well-intentioned; however, fraud and abuse continues to plague the health care system. As the OIG casts a wider net and moves to address fraud and abuse, honest, well-intentioned health care providers will likely feel the pressure and come under scrutiny necessitating strong and consistent compliance efforts. In addition, providers will need to comply with additional reporting and registration requirements implemented by the Centers for Medicare and Medicaid Services ("CMS") to address identified weaknesses in CMS provider enrollment and oversight.

Noteworthy Settlements

An Additional Nine Hospitals – Seven States to Pay More than \$9.4 Million to Resolve False Claims Act Allegations Related to Kyphoplasty – National Investigation Underway

Kyphoplasty is a minimally-invasive procedure used to treat spine fractures. The allegations in the case were that the health care facilities submitted false claims for the Kyphoplasty procedures and overbilled the Medicare program by performing the procedures in the inpatient setting. According to the government, the Kyphoplasty procedures can in most cases be performed safely and effectively in an outpatient setting where reimbursement for the procedure is lower. From the government's perspective, these providers based patient admission decisions on Medicare payment rather than medical necessity and the level of care needed. In addition to the settlement with the individual providers, Medtronic, who acquired the company that manufactures the kits used in the Kyphoplasty procedures, also agreed to pay \$75 million dollars to settle allegations that the company promoted this billing strategy to physicians.

Physician Consultants – DOJ and OIG's Latest Targets

The past several years have seen a number of investigations and settlements with medical device manufacturers. A natural extension of these investigations is looking at the relationships between medical device manufacturers and the physicians who play such a valuable role in advancing medical device development. The OIG has stated publically that it intends to focus its efforts on individual bad actors as well as the larger companies and providers. The OIG has long-standing concerns with physician consulting agreements and physicians receiving payments from medical device companies are not sheltered from anti-kickback liability. Payments that are above fair market value for the services provided or for services not rendered (sham consulting arrangements) may constitute illegal payments for referrals. In a recent OIG settlement, an orthopedic surgeon agreed to pay \$650,000 to settle allegations



that the surgeon solicited and received payment from medical device manufacturers in exchange for the use of the manufacturer's products.

New Registration and Reporting Requirements – Are you ready?

July 6 Deadline for Physician and Non-Physician Practitioners to Enroll in PECOS

Medicare-participating physicians and non-physician practitioners who have not registered with the Provider Enrollment, Chain and Ownership System (PECOS) by July 6, 2010 can no longer order or refer patients for durable medical equipment (DME) or home health services that will be reimbursed by Medicare. Medicare contractors are in the process of sending out letters to physicians regarding the July 6 deadline, in follow up to the publication of an interim final rule by CMS in May. It is important not to wait until the last minute to enroll -- PECOS registration can be a time consuming process. Physicians who have not updated their Medicare enrollment record since November 2003, are likely not in PECOS. CMS maintains a PECOS database that can be used to verify enrollment status.

Risk Management Write-Offs and Payments Can Trigger Section 111 Mandatory Reporting

CMS requires entities, including hospitals and other providers, that meet the definition of "responsible reporting entities" (RREs) to register as an RRE and begin reporting certain settlements, judgments and awards, as well as the assumption of ongoing responsibility for medicals (ORM) to Medicare beneficiaries made on or after October 1, 2010. Although reporting is not required until January 1, 2011, it is important now to determine whether and to what extent an entity will be required to report, bearing in mind that the way an entity handles patient complaints or claims through its risk management process can trigger reporting obligations. Significantly, CMS has been casting a very broad net in recent guidance, using its authority under Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 and Medicare Secondary Payer (MSP) laws. Last month, CMS issued an Alert stating that risk management write-offs constitute "liability self-insurance" for the purposes of the MSP provisions, thereby triggering potential registration and reporting obligations. The Alert further clarified that risk management write-offs and payments -- including those made solely to enhance good will or reduce the likelihood of a liability claim, even without a formal settlement -- are reportable when there was evidence, or a reasonable expectation, that the Medicare beneficiary has sought or may seek medical treatment as a consequence of the incident giving rise to the risk. Failure to report can lead to serious consequences, including fines of up to \$1,000 per day per claim.

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