KING & SPALDING

Health Headlines

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DOJ Announces $2.5 Billion in Health Care Fraud Recoveries for Fiscal Year 2010 – On November 22, 2010, Tony West, Assistant Attorney General for the Civil Division, announced record-breaking statistics for healthcare fraud recoveries—$2.5 billion in health care fraud recoveries during fiscal year 2010, $4.6 billion in False Claims Act (FCA) recoveries from January 2009 through September 2010, and more than $3 billion in fines, forfeitures, restitution and disgorgement under the Food, Drug and Cosmetic Act from January 2009 through September 2010.

Health care fraud made up 83% of fiscal year 2010's total civil fraud recoveries. Additionally, of the total $3 billion in recoveries for fiscal year 2010, $2.3 billion was recovered in lawsuits brought by whistleblowers under the FCA's *qui tam* provisions. Assistant Attorney General West highlighted recent fraud enforcement efforts, including the interagency Health Care Fraud Prevention and Enforcement Action Team (HEAT), "additional improvements to the False Claims Act and other fraud statutes" made by the passage of the Fraud Enforcement and Recovery Act of 2009, and the passage of "additional provisions to aid the Government in redressing fraud on the nation's health care system" in the Patient Protection and Affordable Care Act (PPACA). He specifically highlighted PPACA's revisions to the FCA's public disclosure bar and the Anti-Kickback Statute.

These statistics underscore the significant focus of regulators in investigating and prosecuting health care fraud allegations and likely will further encourage whistleblowers to bring claims under the FCA. DOJ's press release is available by clicking here.

Reporter, *Mike Paulhus*, Atlanta, +1 404 572 2860, mpaulhus@kslaw.com.

CMS Issues Stark Law Disclosure Requirements for In-Office MRI, CT and PET Tests in Today's Federal Register – CMS promulgated a final rule implementing Section 6003 of the Patient Protection and Affordable Care Act (PPACA), which amends the Stark law to require physicians who refer Medicare patients for in-office magnetic resonance imaging (MRI), computed tomography (CT), or positron emission tomography (PET) tests to provide those patients with a list of at least five alternative suppliers in the area. Failure to provide notices when required would constitute a Stark Law violation. The final rule appeared in the 2011 Medicare Physician Fee Schedule which was put on display on November 2, 2010 and published in today's (November 29, 2010) Federal Register. A link to the final rule is available by clicking here. The disclosure requirement will be effective for referrals made beginning January 1, 2011.

Generally, the Stark law prohibits physicians from referring Medicare patients for certain "designated health services" to any entity with which the referring physician, or his or her immediate family members, has any direct or indirect financial relationship. The entity furnishing the designated health services is also prohibited from billing Medicare for the services referred by the related physician. There is an exception, however, for in-office ancillary services if certain supervisory, location and billing requirements are met. Section 6003 of PPACA modified that exception to require physicians who refer for in-office MRI, CT or PET scans to provide their Medicare patients at the time of referral a written list of at least

five other suppliers who furnish those services within 25 miles of the physician's office. The notice must be reasonably understandable to patients and include the names, addresses and telephone numbers of at least five other suppliers that provide the referred services. If fewer than five suppliers are located within the 25 mile radius, then all suppliers within this area should be listed. Hospitals are not included within the definition of supplier so, while they may be included in the notice, they do not count in determining whether at least five suppliers are listed.

The preamble to the final rule reiterates that a written notice should be presented to the patient each time a CT, MRI or PET referral occurs, even if prior disclosures had been made to the same patient. If a referral is made by phone, a written notice should still be made by mail or even e-mail and documented.

CMS noted in the preamble that physicians should document their compliance with the disclosure requirement but did not adopt the provision in the proposed rule that would have required the maintenance of a signed disclosure form from the patient. In addition, CMS encouraged, but did not require, physicians to update the list of alternative suppliers annually and to consider whether the listed suppliers are accepting new Medicare patients.

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OIG Issues Report and Recommendations on Adverse Events in Hospitals – As required by the Tax Relief and Health Care Act of 2006, the Office of Inspector General (OIG) of the Department of Health and Human Services has issued a report entitled "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries" (OEI-06-09-00090). Although the statute requires that OIG report on the incidence of "never events"—a list of serious events, *e.g.* surgery on the wrong patient, that "should never occur in a health care setting," according to the National Quality Forum—in its most recent report the OIG analyzed adverse events of varying degrees of seriousness. In particular, the OIG attempted to estimate the incidence of adverse events for hospitalized Medicare beneficiaries nationwide and to determine the preventability and cost of such events. Using this information, the OIG made a series of recommendations to the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS).

The OIG found that around one in every seven hospitalized Medicare beneficiaries experienced adverse events during their hospital stays. In particular, OIG estimated that 1.5 percent of hospitalized Medicare beneficiaries experienced an adverse event that resulted in death. Another one in seven experienced events that resulted in some degree of temporary harm. The costs associated with these events totaled $324 million in one month alone, representing an estimated 3.5 percent of Medicare's total expenditure for inpatient care. Of the patients who suffered from either an adverse event or a temporary harm event, more than half suffered an event that could not be prevented, while 44 percent suffered events deemed clearly or likely preventable. Preventable events were linked most commonly to a lack of patient monitoring, substandard care, or medical error.

In order to reduce the incidence of adverse events and to lower the amount of Medicare funds devoted to them, OIG made three recommendations to AHRQ and CMS. First, rather than focusing on a specific list of adverse events, both agencies should broaden their safety efforts to include all types of adverse events. Second, the agencies should improve their mechanisms for identifying the occurrence of adverse events. For example, AHRQ should put in place a specific protocol for identifying and analyzing these events. Meanwhile, CMS should require that Quality Improvement Organizations (QIOs) use Present on Admission (POA) indicators to identify the incidence of adverse events at individual hospitals. Third, CMS should incentivize the reduction of adverse events. For example, CMS should expand the list of hospital-acquired conditions. In addition, CMS should more rigorously enforce the condition of participation in Medicare and Medicaid that requires hospitals to have programs that demonstrate quality improvement.

Both AHRQ and CMS agreed with OIG's recommendations. AHRQ called the incidence of adverse events "alarming." CMS responded to the report by stating that it will "aggressively pursue" broadening the scope of its patient safety efforts and incentivizing hospitals to reduce the incidence of adverse effects.

The report is available by clicking here.

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Medicare Incentive Payment Programs for Primary Care and Surgical Services Effective in 2011 – Effective January 1, 2011, qualifying primary care physicians and non-physician practitioners submitting claims to Medicare will be eligible to receive an incentive payment for primary care services. Section 5501(a) of the Affordable Care Act added a new paragraph (x) to section 1833 of The Social Security Act, "Incentive Payments for Primary Care Services" (the PCIP program), which states that, in the case of primary care services rendered on or after January 1, 2011 and before January 1, 2016 by a primary care practitioner, there also will be paid on a monthly or quarterly basis an amount equal to 10 percent of the payment amount for such services under Part B. Section 5501(a)(2)(B) of the Act defines primary care services by Current Procedure Terminology (CPT) codes. A list of eligible codes can be found on page 3 of the MLN Matters Number MM7060, available by clicking here. To receive the incentive payment, the primary care services must have accounted for at least 60 percent of the allowed charges under the Physician Fee Schedule for the practitioner during the time period.

In conjunction with the PCIP, the new Health Professional Shortage Area (HPSA) Surgical Incentive Payment Program (HSIP) will be implemented in 2011. Section 5501(b) of the Affordable Care Act revises section 1833(m) of The Social Security Act and provides for additional incentive payments (on a monthly or quarterly basis) for major surgical services furnished by general surgeons in Health Professional Shortage Areas in an amount equal to 10 percent of the payment for physicians' professional services under Part B. The incentive payments will also apply to surgical procedures furnished in HPSAs by eligible surgeons who have reassigned their billing rights to a Critical Access Hospital paid under the optional method. To access the MLN Matters Number MM7146 for more detail on this program, click here.

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King & Spalding Hosts Managed Care Roundtable – On Friday, December 10, 2010, King & Spalding will host a Roundtable in its Atlanta offices featuring speakers from the Washington, D.C. and Atlanta managed care and antitrust practices on current developments in the managed care industry relevant to providers and payors. For more information and to register, please click here.

This bulletin provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.

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