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Too Much Care? Stepped Up Medical Necessity Fraud Litigation Against Hospitals

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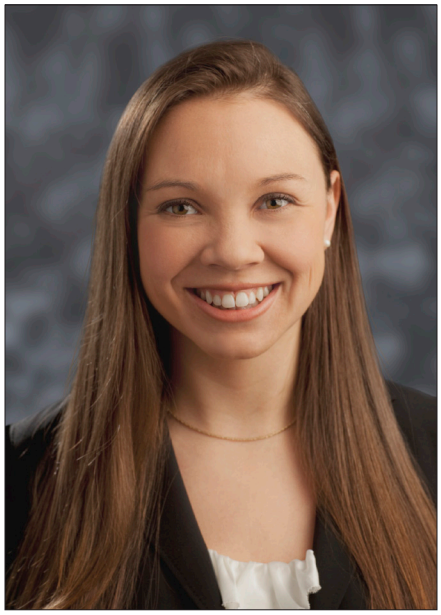

The view of fraud prosecution's new frontier is becoming clearer with the announcement of substantial new enforcement actions and settlements focusing on the hospital's role in the performance of allegedly unnecessary procedures. These cases should cause providers to take a fresh look at the intersection of risk management, peer review and billing where medical procedures are alleged to have been unnecessary or in excess of the patient's needs. Hospitals should evaluate how alleged unnecessary services reported through quality assurance channels might create repayment obligations and fraud prosecution risk.

In August, the U.S. Department of Justice ("DOJ") reported that Peninsula Regional Medical Center of Salisbury, Maryland paid $1.8 million to settle allegations that the hospital knew of, but failed to remediate staff members' concerns regarding a cardiologist's improper stent procedures. The physician was criminally prosecuted and convicted in July of six health care fraud offenses involving the heart stents, including falsifying patient records, performing unnecessary operations, and billing private and public insurers for these procedures. The DOJ accused the hospital's senior medical staff of failing to fully investigate the reports, and therefore, the submission of false claims for the associated procedures. In addition to repaying the amounts billed for the cardiac procedures, the hospital signed a Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services, Office of the Inspector General ("OIG"), which, notably, requires it to appoint a full-time "physician executive" to police hospital quality of care issues, and a board-certified cardiologist to direct the cath lab.

Cardiac stent insertion appears to be a hot issue in this realm. In December 2010, yet another Maryland hospital, St. Joseph's Medical Center, was the unwitting recipient of DOJ's attention where it self-reported to the government and to its patients that an employed cardiologist reportedly implanted unnecessary stents in 585 patients between January 2007 and May 2009. The

DOJ settled with St. Joseph for $22 million. This settlement related to these allegations as well as those that St. Joseph's paid illegal kickbacks to the associated cardiology group by overpaying for their practice and artificially inflating physician salaries above fair market levels. St. Joseph's woes did not end there, as the allegedly victimized patients have filed multiple suits against the hospital, as has the allegedly profligate cardiologist, who believes he has been defamed by the hospital's self-reporting.

Even self-examination raises thorny questions. Excela Health of Pennsylvania initiated audits of 100% of the stent procedures performed by two staff cardiologists after learning of suspected problems. The audit, which cost Excela approximately $500,000, revealed that about 10% of the coronary stents may have been unnecessary. In its June 2011 press release, Excela explained that the patients were notified and offered additional consultation services. The health system also plans to reimburse the insurers. As far as we are aware, the DOJ has not yet knocked on Excela's door.

The government has also initiated nationwide campaigns related to the medical necessity of performing certain procedures on an inpatient rather than outpatient basis, allegedly because the reimbursement for inpatient services is higher. In one such investigation, nine hospitals have agreed to pay more than $9.4 million to settle allegations that they improperly billed kyphoplasty procedures as inpatient procedures in order to increase Medicare reimbursement. Kyphoplasty, the government contends, is a minimally invasive procedure to treat spinal fractures that often can be performed safely as a less costly outpatient procedure. The government is staking out this position despite the fact that Medicare quality improvement organizations accepted the procedures performed on an inpatient basis, and InterQual admission criteria, among others, treated them as being performed on an "inpatient only" basis. Similarly, the DOJ is currently reviewing whether cardiac defibrillator implants were performed in a manner that comported with a Medicare national coverage determination policy. Medicare Recovery Audit Contractors are looking at these and similar procedures as well.

It has long been common wisdom that, because medical necessity cases usually devolve into a battle of experts, such cases are poor candidates for fraud prosecution. However, as hospitals' compliance departments have become more effective in dealing with the more prosaic coding and coverage issues, the government is paying more attention to medical necessity as a basis for not only coverage determinations, but also the imposition of penalties. Providers can take a number of steps to mitigate their risk with respect to billing for medically unnecessary procedures:

1. Educate physicians about proper medical record documentation. Such documentation is essential to supporting medical necessity decisions.

2. Conduct regular audits (either internal or external) and pay attention to high-cost procedures that generate significant government reimbursement, or identify physicians who may be outliers in the incidence of such procedures;

3. Promptly and thoroughly investigate complaints or reports of potentially improper procedures;

4. For employed physicians, periodically review whether compensation levels are consistent with fair market value, as overpayment may lead to an inference that the hospital is encouraging unnecessary care; and

5. Implement policies requiring disclosure of financial relationships between physicians and pharmacy and device vendors. The pending implementation of the Payment Sunshine Act (§6002 of the Accountable Care Act), will assist as manufacturers will be required to disclose to the government information about all but the most nominal payments made to physicians. Nevertheless, a hospital's affirmative knowledge of these relationships may enable it to identify suspicious procedures and/or billing practices before it is too late.

Medically unnecessary care in the hospital raises a host of legal and political issues, fraud being only one. Assistance from counsel to address those issues should be sought early and often.

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