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HOSPITAL ALERT: DOJ INVESTIGATION OF KYPHOPLASTY ONE-DAY STAYS

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The Health Care Department at Murtha Cullina is pleased to provide clients and friends with information about topics of interest in the health care area.

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Kyphoplasty is a minimally invasive procedure, done under intravenous anesthesia in which a balloon is inserted into the site of a vertebral compression fracture and the area is reinforced with bone cement. Kyphon, the manufacturer of the surgical "kits" used in the procedure, was subsequently bought by Medtronic.

In May 2008 Medtronic agreed to pay $75 million to settle a whistleblower lawsuit that had been joined by the government. The whistleblowers (two former Kyphon marketing executives) alleged that, because the high costs of the kits were not adequately covered by Medicare outpatient rates, Kyphon's marketing staff induced physicians and hospitals to admit patients for medically unnecessary one-day stays. The government allegations included charges that the company: (1) told physicians the procedure should be done on an inpatient basis; (2) taught physicians to mischaracterize it as an "open" procedure in parts of the country where Medicare carriers were not yet covering the procedure; (3) insisted physicians perform a bone biopsy in every case (Kyphon also manufactures a tool used for this procedure); (4) advised physicians on how to document co-morbidities and other risk factors to justify an admission; and (5) provided free equipment, "marketing support" services, lucrative consulting agreements and other kickbacks to high-performing physicians.

As a spin-off of the settlement, the Office of the United States Attorney General in the Western District of New York has spearheaded a nationwide investigation aimed at hospitals that performed a large number of the procedures on inpatients with one-day stays. The government contends that the overwhelming majority of such cases could have been done on an outpatient basis. When performed on an inpatient basis, Medicare reimburses $12,000 to $15,000 for kyphoplasty under MS-DRGs 517, 516 or 515. By contrast, APC payments for outpatient kyphoplasty range from $2,500 to $4,500.

We have been in contact with several target hospitals and their counsel and are aware of only one settlement so far. After an initial inquiry by the US Attorney's office, HealthEast reportedly conducted an internal audit and in May 2009 repaid $2.28 million to settle its investigation prior to a demand for repayment by the government. That voluntary repayment is now being held out as a model of cooperation by the US Attorney's office. Other target hospitals are being offered the following two options:

Option 1

(a) conduct a self-audit on the one-day stay records already submitted and determine what *percentage* of those cases should have been billed as outpatient cases (expected to be between 61% and 81% of the one-day stays);

(b) if the percentage is satisfactory, the government will permit the total overpayment amount to be reduced by an "offset" based on the APC payment rate for 2005 (by which time outpatient rates had improved) for these cases;

(c) the actual difference will be multiplied by 2.25 for a False Claims Act penalty;

(d) a positive recommendation will be made by DOJ to the OIG regarding the hospital's cooperation.

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Option II

(a) lose the "offset";

(b) face a treble False Claims Act penalty plus the $10,000 - $15,000 per claim fine the FCA permits;

(c) no positive recommendation to the OIG (which could mean a more burdensome Certification of Compliance Agreement (CCA) for the hospital).

Hospitals generally give considerable deference to physician decisions to admit a patient as an inpatient. Although kyphoplasty can be performed as a same-day procedure, some patients would be appropriate for inpatient admission based on advanced age and co-morbidities that increase the risks associated with a surgical intervention and general anesthesia. Indeed, until May 2008, InterQual (a private set of screening criteria for appropriate level of care) listed kyphoplasty on its "inpatient list." Several Medicare quality improvement organizations (QIOs) have told hospitals to use InterQual criteria to analyze the need for inpatient care, apparently indicating that the government had adopted the InterQual criteria as reliable guidance.

Further, on July 30, 2008, CMS listed kyphoplasty and a related procedure, vertebroplasty, as procedures on which it was considering issuing a national coverage determination. CMS commented that "typically, vertebroplasties are performed in an outpatient setting, while kyphoplasty typically requires hospital admission."

How does a retrospective review of whether inpatient admissions were medically necessary lead to an allegation that the target hospitals violated the False Claims Act? While the Department of Justice agrees that individual physicians order the level of care, they point out that hospitals have a duty under the Medicare Condition of Participation to have a utilization review process. The argument appears to be that if target hospitals billed one-day stays as inpatient — rather than re-characterizing them as outpatient or observation status and billing under OPPS rather than the inpatient DRG — the hospital was acting "recklessly" or "in deliberate ignorance" of the truth or falsity of the accuracy of the claims submitted (these are part of the False Claims standard for "knowing" submission of a false claim).

And that's the sticking point for most of the attorneys with whom we spoke. Many hospitals would be willing to conduct a retrospective self-audit and make repayment if some stays could have been billed as outpatient. But since the admitting *physician* orders the level of care, and UR staff applying InterQual criteria found that the requirements for admission were met, how can it be said that the hospital *knowingly* submitted a false claim to Medicare? One-day stays are not inherently improper, but they have been the target of considerable interest by RAC contractors during the demonstration period.

What you should be doing **now**:

Produce an internal report showing (1) the number of kyphoplasty cases performed since 2000; (2) Level of Care (inpatient, outpatient, outpatient observation/extended recovery) and who ordered/determined the appropriate Level of Care; (3) CPT codes submitted; (4) payer; (5) reimbursement received; (6) UR criteria that was then relied upon by your staff.

Consider whether to review past kyphoplasty cases now rather than await the US Attorney. Consider whether this should be done under outside attorney supervision so as to render the review confidential. Consult with knowledgeable attorneys to develop a plan.

If you have any questions, please contact Paul Knag at 203-561-6438 or Elizabeth Neuwirth at 203-653-5400.

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