

# MEDICARE COMPLIANCE

## Hospital Settles FCA Allegations Over Surgery; Feds: MD Scared Patients Into OR

This time, patients were the whistleblowers in a false claims lawsuit, and it has led to both a settlement with an Ohio hospital that billed Medicare and Medicaid for allegedly medically unnecessary spine procedures and to criminal charges against the surgeon who performed them.

West Chester Hospital in Cincinnati and its parent company, UC Health, agreed to pay \$4.1 million to settle the false claims allegations, the Department of Justice (DOJ) and U.S. Attorney's Office for the Southern District of Ohio said Oct. 9. The surgeon embroiled in the case, Abubakar Atiq Durrani, was indicted by a grand jury in 2013 for health care fraud and was arrested, but after his arraignment, he went on the lam and is apparently still a fugitive, DOJ says.

Durrani allegedly duped patients into spine surgeries they didn't need, leaving them damaged and in pain, according to the false claims complaint and indictment. He allegedly told some cervical spine patients their head "would fall off" in a car accident "because there was almost nothing attaching the head to the patient's body," the indictment contends.

Medical necessity continues to be a priority for DOJ as it investigates more civil and criminal cases in tandem, with an eye on patient harm. "This really underscores what the government indicates will be a priority of law enforcement: parallel proceedings," says former federal prosecutor Brian McEvoy, an attorney with Polsinelli in Atlanta. In September 2014, Assistant Attorney General Leslie Caldwell said that all False Claims Act lawsuits filed by whistleblowers will be immediately reviewed by prosecutors in the criminal division in addition to the usual review by lawyers in the civil division (*RMC 9/22/14, p. 1*). Future civil or criminal cases against hospitals also may mean criminal charges for executives in light of a DOJ policy change. Last month, in the so-called Yates memo, DOJ said it won't settle civil and criminal corporate fraud cases unless corporations cough up names of "culpable" individuals, who will be held accountable (*RMC 9/14/15, p. 1*). They won't be easy cases to make, McEvoy says, but "I think they will be able to try. It is a scary proposition for health care executives

nationwide who, in many instances, will be presumed to have had criminal knowledge they may not have."

In this case, only the corporation settled allegations, which West Chester Hospital and UC Health denied in the settlement. The surgeries were performed between May 27, 2009, and April 25, 2013; West Chester Hospital yanked Durrani's privileges in March 2013.

The false claims lawsuit was filed by some of Durrani's patients — Ralph David Scott, Cory Wright, Rebecca Applegate and others — who underwent spine surgery. They alleged Durrani performed spine surgery using a drug that was not FDA approved for the type of surgery he performed, and that the surgeon and West Chester Hospital billed Medicare for the surgeries even though they were not covered or reasonably necessary.

According to the complaint, the surgeon implanted spinal rods, screws and cages during spine surgery and used a drug called BMP-2, which is marketed by Medtronic under the name Infuse. BMP-2 was not FDA approved for cervical and thoracic spine surgeries, the complaint says. Its use was FDA approved only "for a limited procedure, performed on a limited area of the spine, using specific components," the complaint says.

There are problems with using the drug off-label, alleged the complaint. Infuse "frequently causes excessive or uncontrolled...bone growth on or around the spinal cord," the complaint alleged, which can compress the nerves. If that happens, patients may suffer from pain, spasms, cramps and paralysis.

The whistleblowers also allege Durrani and the hospital "falsely marketed Medtronic pedicle screw hardware to" two of them as safe for their cervical spine procedures.

### Patients Allegedly Misled About Surgery

For example, Durrani performed procedures on Scott at West Chester Hospital using Medtronic hardware and BMP-2 in January and September 2010. The second procedure was an anterior cervical fusion, which involved implanting a cervical pedicle screw at the patient's C6-C7 vertebrae. Use of pedicle screws in the cervical spine is not FDA approved except when the patient suffers

extreme trauma or needs end-of-life pain control, which was not relevant here, the complaint said. The surgeon and hospital were paid for the procedure, even though it was medically unnecessary, the complaint alleged.

Durrani is innocent until proven guilty. But the allegations in the indictment paint a picture of the surgeon as sort of a con man. "Durrani would persuade the patient that surgery was the only option, when in fact the patient did not need surgery," the indictment alleged. The surgeon described the patients' medical situations as "urgent," telling them "falsely" they were at risk of "grave injuries without the surgery." Radiology reports were not read at all or were disregarded, even though he ordered them, according to the indictment. "Durrani would provide his own exaggerated and dire reading of the patient's imaging that was inconsistent with or plainly contradicted by the report written from the radiologist."

Also, operative notes and treatment records allegedly had false statements about diagnoses, procedures and instruments used to perform the procedures. "Many of the patients treated by Durrani for back and neck pain were left in a worse position due [to] the unnecessary surgeries he performed," the indictment alleged.

For example, Durrani diagnosed "patient 3" with rotational instability at the C1-C2 level, performed a posterior spinal fusion with instrumentation and documented it in operative notes and medical records. But imaging and medical records revealed that the patient didn't have instability and didn't require surgery, the indictment alleged. The surgery resulted in "serious bodily injury to patient 3" while lining Durrani's pockets, according to the indictment.

Durrani, who allegedly performed medically unnecessary procedures on patients in Kentucky and Ohio, was charged with five counts of health care fraud and five counts of making false statements in health care matters, the U.S. Attorney's Office said.

### **Screening Is Suggested 'at Every Portal'**

The false claims settlement and the indictment are the latest in a series of cases challenging the medical necessity of procedures. In June, Michigan neurosurgeon Aria Sabit pleaded guilty to health fraud for performing medically unnecessary spinal fusions (*RMC 6/1/15, p. 1*). Several hospitals have settled false claims cases in connection with medically unnecessary stent surgeries (*RMC 8/4/14, p. 1*), and hundreds of hospitals are on the cusp of resolving false claims allegations of billing for medically unnecessary cardiac defibrillator implants (*RMC 10/5/15, p. 1*).

"The medical necessity of procedures is even more difficult for a hospital to evaluate than physician decisions regarding hospital admissions, and those are not

easy," says San Francisco attorney Judy Waltz, with Foley & Lardner LLP. Unlike many commercial payers, Medicare doesn't preauthorize procedures, so there is no process for evaluating the recommendation of surgery before agreeing to pay for it. "Hospitals clearly don't want to discourage referrals to their hospitals or make it too much of a hassle to be admitted for a lucrative procedure by a physician who probably specializes in these procedures," she says. "Hospitals can't insist on a second opinion before they admit patients for surgery," although they can make some moves to protect themselves, such as pre-op testing for MRSA so they aren't penalized for hospital-acquired conditions.

It takes screening procedures "at every portal of entry" to guard against medically unnecessary procedures and admissions, says Elizabeth Lamkin, CEO of PACE Healthcare Consulting. For example, when patients present to the hospital for tests or procedures, a care manager or registrar nurse should ensure the diagnosis is considered medically necessary or determine if procedures are on the inpatient-only list. Even with safeguards, hospitals may trip up on procedures. "Surgery and radiology are sort of the donut hole that gets missed," she says. Audits of surgery departments often find there is no history and physical in the medical records. "We talk about the environment of familiarity," Lamkin says. "Surgeons have relationships with the departments, which don't understand it's their job to make sure patients don't get put into the OR without all the screening in place. They think if there's an order, they're good." But an order isn't enough; patients have to be screened for appropriate utilization and medical necessity, she notes.

For example, the cardiac catheterization lab may not ask for a diagnosis when cardiologists schedule patients for elective cardiac cath. "They may schedule without the appropriate screening triggers, and this is where the cardiologist gets into trouble," Lamkin says. Auditors are denying claims for unnecessary or undocumented cardiac cath. "Hospitals need to have a system where a care manager or someone else looks at the diagnosis to make sure it's appropriate for the cath," she says. On the back end, the cath lab's cardiac committee, which oversees the medical staff, should monitor physician compliance with American College of Cardiology guidelines, such as the percent of normal cath, Lamkin says. If a physician falls outside any of the metrics, find out why. "It's another check and balance," she says.

### **Compliance Is 'a Protection'**

Physician advisers believe they can prevent medically unnecessary services on the front end, "but if they don't know about it, they can't stop it," Lamkin says. It's effective to combine a front-end process with a physician adviser leading the utilization function, educating physi-

cians and building their trust. “You don’t want to alienate doctors, but you have to be truthful and hold them to a regulatory standard that protects them,” she says. “Make sure physicians know the government is out there with well-funded [auditors and enforcers],” and compliance “is a protection the hospital is offering.”

A gag order was issued in the Durrani case, so attorneys for the whistleblowers and hospital could not

comment, said Eric Deters, an attorney for the whistleblowers. UC Health did not respond to a request for comment.

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