

MEDICARE COMPLIANCE

Weekly News and Compliance Strategies on CMS/OIG Regulations, Enforcement Actions and Audits

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PUBLISHER'S NOTE: RMC will not be published next week. The next issue will be dated Oct. 17.

Managing Editor

Nina Youngstrom
nyoungstrom@aishealth.com

Contributing Editor

Francie Fernald

Executive Editor

Jill Brown

Former Hospital CEO Will Pay \$1 Million as More Executives Take Hit in Fraud Cases

In one of the most evocative expressions of the Yates memo, the former CEO of Tuomey Healthcare System agreed to pay \$1 million over the alleged part he played in the sweetheart deals that turned the South Carolina health system inside out, the Department of Justice said Sept. 27. The settlement with Ralph J. Cox III comes almost one year after Tuomey agreed to pay \$72.4 million in connection with a jury finding that it violated the Stark law and False Claims Act (FCA). Cox also will be excluded from Medicare for four years, as the HHS Office of Inspector General works in tandem with DOJ to flex the muscles of the 2015 Yates memo, also known as the Individual Accountability Policy, which is the blueprint for nailing "culpable" individuals as part of corporate fraud cases.

"I would say to executives in health care organizations that they should be careful out there," says Fort Lauderdale, Fla., attorney Gabriel Imperato, with Broad and Casel. "This is the latest poster child for the applicability of the Individual Accountability Policy and for OIG's exclusion of the individual all based on his involvement in not preventing and not correcting a significant organizational compliance deficiency: violations of the Stark law."

continued on p. 7

Overlapping Surgery Faces Scrutiny; Surgeons Make Decisions But Have Limits

Surgeons make the call whether it's safe and compliant to perform overlapping surgeries, with oversight from hospitals, but the government is looking over their shoulders. Medicare pays for two overlapping surgeries if surgeons are present at the "key or critical portions" of both, and they are available to the residents who take over the rest of the procedure. Now questions are being raised about the extent of overlapping surgeries and compliance with Medicare requirements.

Already two false claims lawsuits have settled and a third one is pending. Meanwhile, Senate Finance Committee Chairman Orrin Hatch (R-Utah) has been poking around overlapping surgeries, asking teaching hospitals about their policies and procedures and the volume of overlapping surgeries they perform. "This seems to be gaining momentum and traction," says Atlanta attorney Sara Kay Wheeler, who is with King & Spalding.

Medicare allows surgeons to bill for two overlapping surgeries if the critical or key portions don't take place at the same time. "When all of the key portions of the initial procedure have been completed, the teaching surgeon may begin to become involved in a second procedure," CMS says in Medicare Transmittal 2303, which describes billing and documentation requirements for Part B payments to physicians who involve residents in services. Meanwhile, a "qualified practitioner performs noncritical components

of the first operation,” such as wound closure, according to the American College of Surgeons. The surgeon or another primary surgeon must be immediately available to assist if their intervention becomes necessary.

There’s no Medicare master list of key or critical portions for surgeries. “What we have done is say the surgeon has to determine what the key portion is,” says Allan Kirk, M.D., surgeon in chief for Duke University Health System in North Carolina. “It has to make sense to the people who practice it, and it has been a pragmatic approach.”

With some surgeries, the key or critical portions are straightforward, Kirk tells *RMC*. “Putting in a Foley catheter before a bowel resection is probably not key or critical, but a Foley catheter during prostate resection could be extraordinarily important. There’s no way to take it out of context and say what’s critical or key,” he says.

And it gets more elaborate. Two surgeons with different specialties may have their hands in the same procedure, each performing key or critical portions, Kirk says. For example, with a laminectomy, the general surgeon performs the spine exposure and the spine surgeon takes

over to do the laminectomy. “The spine procedure was critical for the spine surgeon, but not for the general surgeon, and the exposure was critical for the general surgeon, but not the spine surgeon,” Kirk says. “Particularly in a setting like our hospital, we have many complicated cases and try to combine cases to minimize anesthetic exposure. It doesn’t make sense for the general surgeon to sit idly by while the spine surgeon does his thing.”

Concurrent Surgeries Are Not Permitted

When all is said and done, however, only 4% of surgeries at Duke are overlapping, and concurrent surgeries aren’t permitted. “As we started looking at our practice in concurrent surgery and overlapping surgery — which are two different things frequently confused as one — we had a fairly small number of cases that were even applicable,” Kirk says. With concurrent surgeries, part or all of the key or critical portions of both procedures happen at the same time. “A primary attending surgeon’s involvement in concurrent or simultaneous surgeries on two different patients in two different rooms is inappropriate,” according to the American College of Surgery.

Although surgeons decide on the key or critical portions at Duke, they are held accountable. “We have empowered anesthesiologists to delay cases and empowered surgical chairs to cancel cases if we think they’re moving in a way that’s leaving surgeons to do two things” at the same time, Kirk says. Surgeons could lose surgical privileges if they violate the policy on overlapping surgeries. Scheduling is another part of the compliance equation, he says. Schedulers are not supposed to book two surgeries with the same surgeon simultaneously, or book one surgery at the hospital building and another at Duke’s ambulatory surgery center, which is across the street. “Regardless of the type of overlap, they can’t be immediately available to the building while in another building,” he says.

The documentation also must include the name of the primary surgeon, a confirmation of his or her physical presence for the key or critical portion of the surgery, and a confirmation of the immediate availability of a primary surgeon throughout the surgery.

Duke explains the implications of overlapping surgeries to patients and their families during the informed consent process, Kirk says. “Most patients think about the OR in a simple fashion: The surgeon walks in, does everything and walks out, but the reality is if we did surgery that way, the system would grind to a halt,” Kirk says. “There is more complexity to achieve the best efficiency for the patient.”

Overlapping surgeries is a risk in light of Hatch’s interest and recent enforcement activity, Wheeler says. “We continue to have some enforcement so it should be

Report on Medicare Compliance (ISSN: 1094-3307) is published 45 times a year by Atlantic Information Services, Inc., 1100 17th Street, NW, Suite 300, Washington, D.C. 20036, 202-775-9008, www.AISHealth.com.

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Managing Editor, Nina Youngstrom; Contributing Editor, Francie Fernald; Executive Editor, Jill Brown; Publisher, Richard Biehl; Marketing Director, Donna Lawton; Fulfillment Manager, Tracey Filar Atwood; Production Editor, Carrie Epps.

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an area to put on your work plan," she says. In February, Hatch sent letters to teaching hospitals, asking numerous questions about the number of overlapping surgeries performed and their policies and procedures around them. For example:

- ◆ "How does your hospital decide which portions of a surgery are 'critical or key'?"
- ◆ "How does your hospital define 'immediately available'?"
- ◆ "Explain how your hospital schedules and ensures that a back-up surgeon is immediately available to assist in a procedure, should the need arise" and describe anesthesia practices during the surgeries.

Hospitals were also asked to produce data, including the total number of overlapping surgeries from 2011 to 2015 and the "number of surgeon violations of the hospital's concurrent surgery policy."

Hatch hasn't done anything public yet with the information gathered, and his office didn't respond to RMC's request for comment on its findings. "It sounds like their expectation is you have effective controls," Wheeler says. "If you have an active surgery program, where you believe overlapping surgeries may be in play through the use of residents or physician extenders, then you probably want to consider the questions posed by the Senate Finance Committee to get a sense of your organization's controls in this area." She also recommends reading the *Boston Globe's* Oct. 26, 2015, newspaper article on overlapping surgeries that was cited in Hatch's letter.

Two Cases Have Already Settled

This is not a theoretical risk. Two hospitals have settled cases where overlapping surgery was a factor, and another lawsuit is pending. In July, the University of Pittsburgh Medical Center, University of Pittsburgh Physicians, UPMC Community Medicine, Inc. and Tri-State Neurosurgical Associates-UPMC, Inc. agreed to pay \$2.52 million to settle false claims allegations that partly involved overlapping surgeries. "The complaint alleged that certain neurosurgeons employed by UPMC submitted claims for assisting with or supervising surgical procedures performed by other surgeons, residents, fellows, or physician assistants, when those neurosurgeons did not participate in the relevant surgeries to the degree required," the U.S. Attorney's Office for the Western District of Pennsylvania said.

Last year, Medical College of Wisconsin agreed to pay \$840,000 to settle false claims allegations that two of its teaching physicians charged Medicare for performing more than one neurosurgery at the same time (*RMC 1/19/15, p. 1*). The false claims lawsuit was filed by Ganesh Elangovan, M.D., a resident at Medical College of Wisconsin who became a whistleblower after he al-

legedly was put in the position of operating on patients without the presence of the teaching physician. The U.S. Attorney's Office for the Eastern District of Wisconsin took over the case, and the settlement alleges fraudulent Medicare claims were submitted for two neurosurgeons "in performing neurosurgeries that involved residents at Froedtert Memorial Lutheran Hospital," according to the settlement. Medical College of Wisconsin, a Milwaukee-based academic medical center, employs its teaching physicians and is affiliated with several hospitals, including Froedtert Memorial. The neurosurgeons allegedly billed Medicare for the procedures, even though they allegedly weren't there for the key or critical portions, the complaint contends.

And a false claims complaint was filed in March against Advocate Health and Hospitals Corp. in Illinois by a resident turned whistleblower. It isn't a direct hit on overlapping surgeries but raises the issue just the same. The whistleblower, Luay D. F. Ailabouni, M.D., a resident at Advocate Christ Hospital and Medical Center, alleged that some surgeons billed Medicare for assistant surgeons even when residents were available. "Medicare and Medicaid reimbursement is not allowed when the resident performs the duties of an assistant surgeon" because "the salary and expenses of residents in teaching hospitals are reimbursed directly" through direct graduate medical education and indirect medical education payments, the complaint alleged. When residents are unavailable, surgeons may use assistant surgeons and physician extenders and bill separately for their services with modifier 82. But that allegedly wasn't always the case; the whistleblower contends he was often "present and qualified to assist." The Department of Justice declined to intervene in the Advocate complaint.

Controls May Be Faulty

Wheeler says some hospitals may lack controls over documentation of overlapping surgeries, informed consent and limits on the number of overlapping surgeries. "It's really hard to figure this out," she says. "Documentation may not be structured around the key or critical portion of the procedure." For example, the time attending surgeons spend in the surgery may vary, depending on what year the resident is in or his or her skill level, Wheeler says. And overlapping surgeries may look perfectly compliant on the schedule, but "it goes out the window when a trauma comes in," she says.

It's up to hospitals to prove they do things safely and are compliant with applicable Medicare rules because overlapping surgeries are on the radar screen, Wheeler says. "It's coming to a head."

Contact Wheeler at skwheeler@kslaw.com. View the transmittal at <http://tinyurl.com/zjxrjpv>. ♦

Supervision Requirements Bridge Gap Between Compliance, Quality

When Kim Bennion, corporate respiratory care service quality assurance manager and compliance consultant at Intermountain Healthcare, asked clinicians about physician supervision requirements, they more or less shrugged their shoulders. Although physician supervision requirements are a Medicare condition of payment that is supposed to protect patient safety, the front-line staff saw them as compliance niceties. So she set about changing their perceptions, and developed education tools to help outpatient departments improve their compliance with physician supervision requirements.

“There is a delicate balance in what speaks to compliance vs. what speaks to clinical operations,” Bennion said at a Sept. 19 webinar sponsored by the Health Care Compliance Association. “The front-line staff said ‘I don’t care about reimbursement as much as I care about patient safety and high quality care,’ but I reminded them that one without the other doesn’t work. We need funding to keep the business going, and we need high quality patient care. It is the intent for physician supervision [to ensure] high quality, safe patient care.”

Outpatient physician supervision requirements have been around for almost two decades, and they are confusing. In 1997, CMS required supervision for payment of most diagnostic tests under the physician fee schedule, Bennion said, although CMS doesn’t mandate specific supervision levels for diagnostic services in critical access hospitals (CAHs). Supervision was greatly expanded in 2009, when CMS said outpatient therapeutic services provided in hospitals have to be directly supervised by a physician or certain nonphysician practitioners. Only physicians may supervise pulmonary and cardiac rehab.

There are three levels of supervision:

- ◆ **General**, which is under the physician’s overall direction and control, but doesn’t require his or her presence.
- ◆ **Direct**, which requires the physician to be immediately available, interruptible and able to provide assistance.
- ◆ **Personal**, which means the physician is in the room while the service is provided.

A Guide to Complying With Stark Physician Self-Referral Rules

The industry’s #1 resource for avoiding potentially enormous fines and penalties

(looseleaf/CD combo with quarterly updates)

Go to the “Marketplace” at www.AISHealth.com and click on “Books.”

In the wake of the 2009 changes, there was hue and cry from hospitals about the burdens of direct supervision. In response, CMS delayed enforcement of the policy in CAHs and small rural hospitals with fewer than 100 beds, although the enforcement moratorium ended Jan. 1, 2015. CMS also devised a new method for supervising certain outpatient therapeutic services, such as observation and infusion, to reduce the supervision burden. According to the 2011 outpatient prospective payment system regulation, “nonsurgical extended duration therapeutic services” require direct physician supervision only at the “initiation of the service.” When patients are stable and the rest of their treatment can be delivered under general supervision, physicians can shift to the lower supervision level, which can be provided by phone.

But Bennion started from scratch when she visited the outpatient departments — including lab, infusion, endoscopy, cardiovascular and imaging — at the Utah health system. “When we asked what physician supervision was, they said, ‘isn’t that what medical students and residents need when they care for patients?’ We realized they didn’t fully understand what it was. And when we asked if they knew where to find CMS-required levels of supervision, they had no clue. And when we talked about different supervision requirements between diagnostic and therapeutic services, they had no idea,” she said.

Educate Before Auditing

The clinicians also didn’t seem to grasp the difference between the Medicare conditions of participation and the conditions of payment, and they focused on the Joint Commission rather than CMS as if the two aren’t joined at the hip, Bennion said. “We knew our work was cut out for us.” Bennion explained that CMS’s rationale for physician supervision is that it promotes patient safety. The physician is available to step in when necessary and is guiding the care. That had an impact on the front-line staff, she said.

Then came the resources. Bennion and her team developed tools for Intermountain clinicians that were disseminated through the compliance officers who work at the health system’s 22 hospitals and other entities. There’s a fact sheet on physician supervision, a list of answers to frequently asked questions, a self-assessment tool (see box, pp. 5-6) and an attestation form for compliance managers.

“We have tried to bridge the gap between the understanding of supervision and compliance,” she said.

For more information, contact Bennion at Kim.Bennion@imail.org. ◆

Physician Supervision: Intermountain’s Facility Self-Assessment Tool

Kim Bennion, corporate respiratory care service quality assurance manager and compliance consultant at Intermountain Healthcare in Utah, developed this self-assessment tool to help outpatient departments evaluate their compliance with Medicare physician supervision requirements. Contact her at Kim.Bennion@imail.org

Facility: _____ Department: _____ Completed by: _____ Date: _____

FACT 1 This section does not apply to CAHs.

Diagnostic Services

CMS specifies three levels of physician supervision for Outpatient Diagnostic Services which include:

- General Supervision: Under the physician’s overall direction and control, but presence is not required
- Direct Supervision: The supervisory physician must be immediately available, interruptible and able to provide assistance throughout the procedure.
- This means more than managing an emergency
- Personal Supervision: Physician must be in the room during the performance of the procedure

(Reference: Detailed Charge Code Spreadsheet for requirement by charge code/service)

CMS Requirements for Physician Supervision for Diagnostic and Therapeutic Outpatient Services	Y, N or NA	Corrective Action Plan (CAP) If “no,” document plan of corrective action with expected completion date.	Supporting Documentation If “yes,” document supporting policies / procedures / guidelines, forms, reference documents, etc...
Hospital outpatient department services should review the Detailed Charge Code Spreadsheet to verify code use, level of supervision for specific services and volume by facility <ul style="list-style-type: none"> • Is the required level of physician supervision clearly defined for services your department? • Is the supervisor “immediately available”? 			

FACT 2 Supervisory Practitioner (Physician or NPP)

Only required for “Direct Supervision.”

- The supervisory physician/NPP must have, within his/ her State scope of practice and hospital-granted privileges, the knowledge, skills and ability to perform the service or procedure.
- Supervisory practitioners do not need to be in the same specialty as the service, but not all practitioners are qualified to supervise every specialty. They must be capable to take over performance and change direction of the procedure, if needed.

NPPs are defined as: nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwives and licensed clinical social workers (added in final rule).

CMS Requirements for Physician Supervision for Diagnostic and Therapeutic Outpatient Services	Y, N or NA	Corrective Action Plan (CAP) If “no,” document plan of corrective action with expected completion date.	Supporting Documentation If “yes,” document supporting policies / procedures / guidelines, forms, reference documents, etc...
<ul style="list-style-type: none"> • Do Hospital Bylaws, credentialing and documented training exist for services supervised by qualified physicians or NPPs? • Is the designated supervisory practitioner able to furnish assistance and direction and not merely manage an emergency? 			
<ul style="list-style-type: none"> • Does the department periodically confirm the availability of the supervising practitioner? • What type of internal monitoring process exists to verify which supervising practitioners are scheduled to supervise services on any given day? • Who is responsible to monitor facility/department compliance? • How often is this monitored? • How is the monitoring documented? 			

FACT 3 Direct Supervision

There is no current requirement for diagnostic supervision in CAHs

Direct supervision means that the physician/NPP must be “immediately available” to furnish assistance and direction throughout the performance of the procedure. CMS does not specify the practitioner’s location in time or distance, but does not allow for telephone or other modes other than in person.

Diagnostics:

Applies to diagnostic services unless General or Personal Supervision is required. (Reference: Detailed Charge Code Spreadsheet for requirement by charge code/service)

- Only a physician can provide supervision for diagnostic services.

Therapeutics: All outpatient therapeutic services (includes CAH) require direct supervision. There are four exceptions (listed below).			
Therapeutic Exception #1 A Non-physician practitioner (NPP) may only supervise outpatient therapeutic services that they personally are able to perform in accordance with State law and hospital granted privileging.			
CMS Requirements for Physician Supervision for Diagnostic and Therapeutic Outpatient Services	Y, N or NA	Corrective Action Plan (CAP) If "no," document plan of corrective action with expected completion date.	Supporting Documentation If "yes," document supporting policies / procedures / guidelines, forms, reference documents, etc...
<ul style="list-style-type: none"> Does the department utilize NPPs? If so, note discipline. Do they serve as supervisory practitioners for any services requiring Direct Supervision? If so, list services. Are they appropriately qualified (i.e., credentialed, privileged and trained)? 			
Therapeutic Exception #2 This section applies to ALL hospitals including rural and CAH. Rehabilitation: Pulmonary, Cardiac, and Intensive Cardiac Rehab can only be supervised by a MD or DO.			
CMS Requirements for Physician Supervision for Diagnostic and Therapeutic Outpatient Services	Y, N or NA	Corrective Action Plan (CAP) If "no," document plan of corrective action with expected completion date.	Supporting Documentation If "yes," document supporting policies / procedures / guidelines, forms, reference documents, etc...
<ul style="list-style-type: none"> Are Pulmonary, Cardiac, and/or Intensive Cardiac Rehab offered at your facility? How is physician supervision documented? Do your policies, procedures or guidelines address the level of supervision for these services? 			
Therapeutic Exception #3 Critical Access Hospitals (CAH) and Rural Hospitals: Direct Supervision is required for all therapeutic services. CMS announced enforcement for CAH and rural hospitals with < 100 beds effective January 1, 2015.			
CMS Requirements for Physician Supervision for Diagnostic and Therapeutic Outpatient Services	Y, N or NA	Corrective Action Plan (CAP) If "no," document plan of corrective action with expected completion date.	Supporting Documentation If "yes," document supporting policies / procedures / guidelines, forms, reference documents, etc...
<ul style="list-style-type: none"> Does the CAH/Rural hospital currently provide Direct Supervision for all outpatient therapeutic services? Is the practitioner functioning within their Scope of Practice? 			
Therapeutic Exception #4 Was new for 2011! Two-Level Supervision with descriptors were updated March 10, 2015. Nonsurgical Extended Duration Therapeutic Services Supervision (Two-Level Supervision Option) Exceptions include service codes such as observation services, specific IV's and injections. These services require direct supervision for the initiation of the service followed by general supervision for the remainder.			
CMS Requirements for Physician Supervision for Diagnostic and Therapeutic Outpatient Services	Y, N or NA	Corrective Action Plan (CAP) If "no," document plan of corrective action with expected completion date.	Supporting Documentation If "yes," document supporting policies / procedures / guidelines, forms, reference documents, etc...
<ul style="list-style-type: none"> Will this two-level option be utilized in your facility? If so, in which departments and for which services (codes) will this be utilized? 			
If this exception option is used: <ul style="list-style-type: none"> Direct supervision is provided for "initiation of service" followed by general supervision, once the treating practitioner deems the patient medically "stable." The determination that a patient is stable is considered a medical judgment and is left to the determination of the practitioner. The transition from direct to general should be documented in the patient's medical record (i.e., progress note). Processes and guidelines need to be developed to describe facility implementation (i.e., when is it appropriate to utilize this option and documentation requirements). 			
CMS Requirements for Physician Supervision for Diagnostic and Therapeutic Outpatient Services	Y, N or NA	Corrective Action Plan (CAP) If "no," document plan of corrective action with expected completion date.	Supporting Documentation If "yes," document supporting policies / procedures / guidelines, forms, reference documents, etc...
<ul style="list-style-type: none"> Are there other current services that you believe should be considered as an exception to direct supervision? If so, please explain. An independent committee designated by CMS will consider provider requests for additional codes under this provision annually. 			
NOTE: Chemotherapy, blood transfusions and recovery for surgical services must always be provided under direct supervision. Two-Level Supervision with descriptors and updated as of March 10, 2015.			

CMS Brings Back 68% Solution to Reduce Patient-Status Appeals

If they desire, hospitals again will be able to get paid soon for their disputed patient-status cases instead of waiting months or years for a decision on their appeals.

CMS said Sept. 28 it will do a second round of the hospital appeals settlement process, known the first time around as the 68% solution. "CMS has decided to once again allow eligible providers to settle their inpatient status claims currently under appeal using the Hospital Appeals Settlement process," according to its website. No details were provided, but CMS said they would be forthcoming.

CMS in 2014 offered hospitals 68% of the net allowable amount of denied claims for inpatient admissions if they dropped their appeals (*RMC 9/8/14, p. 1; 9/22/14, p. 6; 9/15/14, p. 1*). It was available to acute care and critical-access hospitals that appealed denials of claims with dates of admission before Oct. 1, 2013, when the two-midnight rule took effect. Once hospitals signed up for the settlement process, they had to include all "eligible" claim denials — patient-status cases — and couldn't cherry-pick. That took appeals out of the Office of Medicare Hearings and Appeals (OMHA), where they now languish for up to three years.

As of Aug. 18, 2016, CMS said it "executed settlements with 2,022 hospitals, representing approximately 346,000 claims," and paid about \$1.47 billion.

Recently lawyers have been urging CMS to consider another settlement process, and asked hospitals to chime in (*RMC 8/15/16, p. 5*). It would take the heat off OMHA, which is under pressure to comply with statutory deadlines that require administrative law judges to decide appeals of claim denials in 90 days, and off CMS, which is embroiled in a court battle with the American Hospital Association over the failure to meet the deadlines (*RMC 9/26/16, p. 8*).

Visit <http://tinyurl.com/p9ha9qh>. ↵

Former Tuomey CEO Pays \$1M

continued from p. 1

Cox is being held accountable for his part in a legal drama that embroiled Tuomey for many years and included two trials and appeals. DOJ first took Tuomey to trial in 2010 (*RMC 4/12/10, p. 3*), alleging it violated the FCA because its employment agreements with 19 part-time physicians didn't comply with the Stark law. In exchange for performing all outpatient procedures at Tuomey Hospital or its other facilities, the specialists were paid an annual base salary that varied according to the net cash collections for outpatient procedures and a

productivity bonus equal to 80% of net collections, and were eligible for an incentive worth up to 7% of their productivity bonus. The FCA complaint, which originated with physician Michael Drakeford, alleged the compensation for the physicians was above fair-market value and took into account the volume and value of their referrals.

The first jury found that Tuomey violated Stark but not the FCA, but the trial court — U.S. District Court for South Carolina — decided it had made an error by not admitting certain evidence and ordered a new trial on the FCA prong of the case at the government's behest. Tuomey appealed to the U.S. Court of Appeals for the Fourth Circuit, which compelled the trial court to start over on both the Stark and FCA issues. The second jury found the health system violated both the Stark law and FCA (*RMC 5/13/13, p. 3*), resulting in a \$237 million payment order (*RMC 10/7/13, p. 1*). Tuomey appealed the verdict to the Fourth Circuit, but it was denied (*RMC 7/13/15, p. 5*). That set the stage for the \$72.4 million settlement and Tuomey's sale to Palmetto Health.

Then DOJ turned to Cox. According to the settlement, the government has civil claims against Cox "arising from his actions as the chief executive officer and a member of the Board of Trustees of Tuomey" in terms of causing the health system to submit claims from Jan.

CMS Transmittals and Federal Register Regulations

Sept. 23 — Sept. 29

Live links to the following documents are included on RMC's subscriber-only Web page at www.AISHealth.com. Please click on "CMS Transmittals and Regulations" in the right column.

Transmittals

Pub. 100-04, Medicare Claims Processing Manual

- Changes to the Laboratory National Coverage Determination Edit Software for January 2017, Trans. 3614CP, CR 9806 (Sept. 23; eff. Oct. 1, 2016; impl. Jan. 3, 2017)
- Update to Hepatitis B Deductible and Coinsurance and Screening Pap Smears Claims Processing Information, Trans. 3615CP, CR 9778 (Sept. 23; eff./impl. Dec. 27, 2016)

Pub. 100-07, State Operations Manual

- Revisions to Chapter 7, Trans. 160SOMA (Sept. 23; eff./impl. Sept. 23, 2016)

Pub. 15-1, Provider Reimbursement Manual - Part 1

- Chapter 22, Determination of Cost of Services to Beneficiaries, Trans. 472P122 (Sept. 23; eff. for services on or after Jan. 1, 2017)

Federal Register Regulations

Notice

- Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2017, 81 Fed. Reg. 65651 (Sept. 23 2016)

1, 2005, through March 28, 2010, that were false because they violated Stark. Specifically, DOJ alleged that Cox entered into the employment contracts because he feared Tuomey would lose “lucrative outpatient procedure referrals” to a new freestanding surgery center. To head them off at the pass, Tuomey paid the physicians too generously for Stark compliance, DOJ alleged. “During the trial against the hospital, the government argued that Cox ignored and suppressed warnings from one of Tuomey’s attorneys that the physician contracts were ‘risky’ and raised ‘red flags.’”

Cox did not admit liability in the settlement.

The former CEO may not be the only Tuomey executive pursued personally for fines, says former federal prosecutor Robert Trusiak, a principal in Health Care Compliance Support in Buffalo, N.Y. The settlement with Cox states he “agrees to cooperate fully and truthfully with the United States’ investigation of individuals and entities not released in this agreement,” which includes providing testimony and interviews. “That suggests there might be more to come as it relates to Tuomey,” Trusiak says. “The book might not be closed.”

As this and other moves against health executives show, the Yates memo is not a false alarm, and this time, it hit close to home, at an acute-care hospital, at the highest level, lawyers say.

“It’s a bit of a warning shot across the bow,” says Los Angeles attorney Charles Oppenheim, with Hooper Lundy & Bookman. “It signals a desire to make individual decision makers accountable.” The Stark angle surprises him a bit because the Stark law is administrative. “But it’s consistent in that the government believes individuals, not just organizations, should be accountable,” Oppenheim says.

Only a week earlier, another Yates memo case hit the streets. The chairman of the board of North American Health Care Inc. (NAHC) agreed to personally fork over \$1 million of the \$30 million that the post-acute care company agreed to pay in a Medicare and TRICARE false claims settlement, and NAHC’s senior vice president of reimbursement analysis will shell out \$500,000, because of their alleged roles in the scheme (*RMC 9/26/16, p. 1*).

Contact Imperato at gimperato@broadandcassel.com, Trusiak at robert@trusiaklaw.com and Oppenheim at coppenheim@health-law.com. ✧

NEWS BRIEFS

◆ **Vibra Healthcare LLC, a chain of 36 long term care hospitals (LTCHs) and inpatient rehabilitation facilities (IRFs), has agreed to pay \$32.7 million to settle false claims allegations, the Department of Justice said on Sept. 28.** Vibra, which is headquartered in Mechanicsburg, Pa., allegedly billed Medicare for medically unnecessary services. LTCHs treat patients who have complex conditions and require long hospital stays; IRFs serve patients who need hospital-level care and rehab services. According to DOJ, from 2006 to 2013, Vibra allegedly admitted patients to five of its LTCHS and one IRF who weren’t eligible for admission, and extended the LTCH patients’ stays unnecessarily. Visit <http://tinyurl.com/zxtlqaj>.

◆ **The HHS Office of Inspector General gave the green light to a company’s proposal to install a computerized point-of-care vaccine storage and dispensing system in physicians’ offices, according to a new advisory opinion (16-09).** Although the arrangement could violate the anti-kickback statute if there were an intent to induce or reward referrals, OIG will not impose sanctions. According to the proposal, the company would enter into two

agreements: one with physicians who have never stocked vaccines before and one with manufacturers of sole-source vaccines. Participating physicians could use the refrigerated vaccine unit free as long as they stocked only vaccines from the manufacturers, who would pay the company a fee every time their vaccine was administered. Although OIG frowns on the provision of freebies to referral sources, it’s letting this slide for several reasons. For example, any sole-source vaccine manufacturer can cut a deal with the company, and if physicians want to use a vaccine by another manufacturer, they can stock it in a different storage unit. Also, the fees are paid by the manufacturers, who aren’t in a position to generate federal program business. Visit <http://go.usa.gov/xKeA4>.

◆ **The HHS Office for Civil Rights has posted a new FAQ on whether a business associate (BA) may block or terminate a covered entity’s access to the protected health information maintained by the BA on behalf of the covered entity.** The FAQ is intended to clarify that “business associates may not use such information in a manner or to accomplish a purpose or a result that would violate the HIPAA Rules.” Visit <http://tinyurl.com/jj9p8cf>.

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