

MEDICARE COMPLIANCE

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

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Former Tenet Execs Indicted in Kickback Case; Allegations Are Seen as ‘Conclusory’

Three health care executives have now been charged in connection with an alleged scheme to pay for referrals of maternity patients to four Tenet Healthcare Corp. hospitals in Georgia and South Carolina, but the Department of Justice is still playing most of its cards close to its chest. The indictments sprang from Tenet’s \$513 million civil settlement and non-prosecution agreement over kickbacks to Clinica de la Mama, a chain of prenatal clinics in the Atlanta area, for patient referrals to the hospitals (*RMC 10/17/16, p. 1*).

DOJ on Sept. 29 said it charged William “Bill” Moore, the former CEO of Atlanta Medical Center, with conspiracy to defraud the United States and pay and receive health care bribes, wire fraud, falsifying corporate books and records, and major fraud. Edmundo Cota, CEO of Clinica de la Mama, was charged with conspiracy to defraud the United States and pay and receive health care bribes, receiving health care bribes and wire fraud. John Holland, former senior vice president of operations for Tenet’s southern states region and CEO of North Fulton Hospital, who was indicted in January (*RMC 2/13/17, p. 1*), now faces additional counts. Charges against him include paying health care bribes, falsifying corporate books and records, and major fraud.

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OCR HIPAA Phase II Audits Find Problems With Notices, Security; Audit Future Is in Doubt

The HHS Office for Civil Rights (OCR) may not implement a permanent program to audit HIPAA compliance by covered entities (CEs) and business associates (BAs), Linda Sanches, OCR’s senior advisor for health information privacy, said at a September conference. Her remarks fly in the face of OCR’s previous pronouncements and expectations.

Former OCR Director Leon Rodriguez says the implication that the long-planned audit program might not be permanent is “problematic.” There’s an expectation under the 2009 HITECH Act that it would be permanent, says Rodriguez, who is with Seyfarth Shaw LLP in Washington, D.C.

To date, OCR has concluded 165 desk audits of CEs and is conducting 41 of BAs, Sanches said in the first public update since the program, begun in 2011, resumed two years ago. And OCR seems uncertain whether onsite audits under Phase II will occur—or when, which was another surprise in Sanches’ comments.

Not surprising in Sanches’ presentation of findings of completed desk audits is that CEs aren’t doing very well with security rule compliance, at least based on documentation they submitted. Privacy compliance is an issue, too. There’s a “huge problem” when it comes to how CEs are handling patients’ rights to access their medical records, Sanches said at the Safeguarding Health Information: Building Assurance through HIPAA Security conference in Washington, D.C.

continued

The HITECH Act required OCR to develop an audit program, but it didn't provide many specifics, stating: "The [HHS] Secretary shall provide for periodic audits to ensure that covered entities and business associates that are subject to the requirements of this subtitle and subparts C and E of part 164 of title 45, Code of Federal Regulations [namely, HIPAA] as such provisions are in effect as of the date of enactment of this Act, comply with such requirements."

Under Phase I of the program, which was completed at the end of 2012, contractors audited 110 CEs on-site; many were found to be noncompliant.

OCR conducted the Phase II desk audits based on previously announced protocols. Meanwhile, findings collected may not be representative of the health care community at large because "most" of the 165 audited CEs were "small physician practices," Sanches said.

She repeated OCR's earlier statements that enforcement is not the purpose of the audit program. "It has really been designed to help you all in compliance and support your compliance work, not as a gotcha program," she said. "We were hoping to identify some [best] practices out there in the industry that we weren't aware of and maybe uncover some risks and vulnerabilities that we weren't aware of, given that most of our

work comes from breach notifications that we receive, and from complaints."

As such, she said, "There may be some other issues out there that we weren't seeing and thought reaching out to the industry [via the audits] would be helpful in that regard."

Still, she noted, "We do have separate authority where if we saw something alarming or some significant noncompliance we could refer [concerns] over to the enforcement arm of our office."

Those officials "could perhaps open a compliance review if they chose," Sanches said.

OCR audited 103 CEs for compliance with the privacy and breach notification rules, and 63 for compliance with the security rule. Ninety percent of the 165 are providers, Sanches said, and "most of them were smaller providers...small physician practices."

The audit program reviewed some "institutions, nursing homes [and] hospitals," she said. According to a slide she presented, 1% of the auditees were clearing houses, and 8.7% were health plans.

Compliance on a Scale of One to Five

The agency used a new system to rate compliance based on documentation, Sanches explained.

"We wanted to come up with a way to help entities understand, basically, how well we thought their activities met our expectations for what compliance should look like," Sanches said. The ratings were deemed to be "something better than just providing a number of how many findings, because that may or may not be very helpful."

The system "is not a formal rating system that is used for enforcement purposes in any way." She cautioned that she was "hedging" as to whether audited CEs are "actually in compliance...because this was just a desk audit. We didn't actually go out." The assessments were based on "how well we thought they were doing" by reviewing the documentation submitted.

OCR used the following criteria for the ratings range from a one to a five, with one being the highest:

- 1: "The audit results indicate the entity is in compliance with both goals and objectives of the selected standards and implementation specifications."
- 2: "The audit results indicate that the entity substantially meets criteria; it maintains appropriate policies and procedures, and documentation and other evidence of implementation meet requirements."
- 3: "Audit results indicate entity efforts minimally address audited requirements; analysis indicates that entity has made attempts to comply, but implementation

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is inadequate, or some efforts indicate misunderstanding of requirements.”

4: “Audit results indicate the entity made negligible efforts to comply with the audited requirements—e.g. policies and procedures submitted for review are copied directly from an association template; evidence of training is poorly documented and generic.”

5: “The entity did not provide OCR with evidence of serious attempt to comply with the Rules and enable individual rights with regard to PHI [protected health information].”

Privacy Compliance Better Than Security?

Overall, OCR “found a broad range of efforts out there,” Sanches said. CEs did a better job with breach reporting than with other measures, for example. “Most did a really good job on providing notifications on time,” which Sanches said was “gratifying.” Specifically, OCR rated 67 of the 103 CEs a 1 for this category.

But they didn’t do quite as well when it came to the content of the notices. Here just 14% earned a 1, while 67 were rated 3-to-5.

With this measure, OCR found that CEs “were not describing what information was actually breached. It isn’t enough to just say to the individual, ‘Your PHI was breached.’ They need to know something more, like was it their name, their SS#, lab results...what actually was the topic of the breach. They do have the right to that information,” said Sanches.

In addition, “there were problems on saying what they could do to mitigate breaches that did occur,” she said. This is a required element of the notification letter.

Regarding notices of privacy practices (NPPs), OCR was “a little surprised” to discover “so many issues with the content,” especially because the agency has issued model notices. Some of the audited notices “do not adequately discuss the individual’s rights,” she said, such as the right to direct information to a third party. Just 2% were rated a 1, while 72% got a 4-5. CEs are required to give patients NPPs and post them on their websites.

Rankings were similar for how CEs handled patients’ requests for access to their medical records.

CEs Are ‘Not Conducting’ Risk Analyses

Moving on, it would appear that the audited CEs essentially flunked the two measures in the security portion. For risk management, approximately 27% of the 63 organizations received the lowest rating based on OCR’s definitions, slightly worse than the 21% that were given the lowest rating for risk analysis.

Similarly, just 1 of the CEs got the highest rating for risk management and none did so for risk analysis.

In some cases, documentation sent to OCR simply stated that a risk analysis “would be done. Often it would not be clear that it was conducted, or that it was conducted regularly. There might be a sort of form that was provided from years earlier but not filled out or just filled out once,” said Sanches. “Sometimes there would be, in fact, a listing of risks but not a rating of potential harm from some of these threats and vulnerabilities, so that didn’t really meet the requirements for a risk analysis.”

CMS Transmittals and Federal Register Regulations Sept. 29 - Oct. 5

Live links to the following documents are included on RMC’s subscriber-only webpage at www.hcca-info.org. Please click on “CMS Transmittals and Regulations.”

Transmittals

(R) indicates a replacement transmittal.

Pub. 100-04, Medicare Claims Processing Manual

- Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 24.0, Effective January 1, 2018, Trans. 3869 (Sept. 29, 2017)
- 2018 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments, Trans. 3870 (Sept. 29, 2017)

Federal Register

Final Regulations

- Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices; Correction, 82 Fed. Reg. 46138 (Oct. 4, 2017)
- Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2018, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, Survey Team Composition, and Correction of the Performance Period for the NHSN HCP Influenza Vaccination Immunization Reporting Measure in the ESRD QIP for PY 2020; Correction, 82 Fed. Reg. 46163 (Oct. 4, 2017)

Proposed Regulations

- Medicare and Medicaid Programs; Revisions to Certain Patient’s Rights Conditions for Participation and Conditions for Coverage; Withdrawal, 82 Fed. Reg. 46181 (Oct. 4, 2017)
- Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics; Withdrawal, 82 Fed. Reg. 46181 (Oct. 4, 2017)
- Medicare Program; Part B Drug Payment Model; Withdrawal, 82 Fed. Reg. 46182 (Oct. 4, 2017)

Notice

- Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2018, 82 Fed. Reg. 45592 (Sept. 29, 2017)

Regarding risk management, “what we were looking for was some action on the results of the risk analysis and documentation that the analysis was revisited regularly and updated as risks changed,” said Sanches. Some organizations were “doing a good job of this, but many seemed to not necessarily understand the fact that risks might change, risks need to be reevaluated and that what was used six years ago may not, in fact, still be the thing you would want to be looking at today.”

She encouraged audience members to use OCR’s security compliance materials available online at <http://tinyurl.com/l3h4kqk>.

Conducting BA audits “is not the end of it,” Sanches said of the audit program. She added “I can’t really say what the long-term structure will look like.”

In a short statement, OCR said the agency will “update our website with audit findings in 2018. The findings will include more information about the types of CEs and BAs audited, lessons learned and best practices. Additionally, onsite audits will be conducted in future rounds of the audit program.”

Visit OCR’s audit website at <http://tinyurl.com/jjgzzxd>. This story was reprinted from *Report on Patient Privacy*, which is also published by the Health Care Compliance Association. For more information, please contact customer service at 888.580.8373. ✧

After Missing Alerts on Sedation Billing, Practice Settles Case for \$1.9M

New York Anesthesiology Medical Specialties in Syracuse, N.Y., has agreed to pay \$1.94 million to settle false claims allegations that it overbilled for moderate sedation services, the U.S. Attorney’s Office for the Northern District of New York said Oct. 3. The settlement tells a story of missed opportunities to learn the requirements for billing the time-based codes from the Medicare administrative contractor (MAC) and external audits.

New York Anesthesiology Medical Specialties (NYAMS), a physician practice that performs pain management and spine and back procedures, billed Medicare for moderate sedation when the physician didn’t spend at least 16 minutes face to face with the patient “and/or when the medical record did not document that there had been at least 16 minutes of face-to-face time” from Jan. 1, 2012, to Jan. 5, 2016, according to the settlement. NYAMS used a billing company, Specialists Operations Consulting Services (SOCS), to code and submit its claims.

“One thing this matter illustrates is the importance of clear lines of responsibility and communication be-

tween a provider and its billing company,” Assistant U.S. Attorney Michael Gadarian tells *RMC*. “The information needed to bill this code properly was available, but the mechanisms were not in place to obtain and process that information.”

Sedation Was Featured in CPT Assistant

Coding for moderate sedation services has evolved over time, says Marion Salwin, director of physician and regulatory compliance at Trinity Health in Livonia, Mich. Until CPT coding changes in 2017, moderate sedation services were described in the CPT code book as “provided by the same physician performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient’s level of consciousness and physiological status.” They were billed under 99143 (for patients younger than 5 years of age, first 30 minutes intraservice time) or 99144 (for patients age 5 years or older, first 30 minutes intraservice time). Each additional 15 minutes was reported with CPT code 99145.

“Since this is a time-based code, the physician must document the amount of time the service is being provided; the concept of the ‘16-minute rule’ means that the service can be billed when at least one half of the required time has elapsed,” says George Blake, a specialist master with Deloitte & Touche. “Since this code is reported for the first 30 minutes of sedation time, more than one-half of the required time (or 16 minutes) must be documented before it can be reported.” As with all time-based codes, if the services are not documented or documented accurately, “it’s easily audited and discoverable,” Salwin says.

Even though information about the 16-minute face-to-face requirement was out there, NYAMS, which does business as New York Spine and Wellness Center, allegedly wasn’t paying attention, according to its settlement with the U.S. attorney’s office.

Sedation came up in an October article in *CPT Assistant*, a publication of the American Medical Association (AMA). The article stated that 16 minutes or more of moderate (conscious) sedation services must be provided to get paid for CPT code 99144. “NYAMS did not subscribe to or otherwise receive the *CPT Assistant* publication,” the settlement said.

In February 2012, National Government Services, the MAC for New York (and other states), posted an alert on its listserv explaining that providers had to perform and document 16 minutes of face-to-face time to bill under 99144, consistent with *CPT Assistant*, according to the settlement. NGS kept the listserv notice on its website for about one year.

“No one at NYAMS subscribed to the NGS list-serv,” the settlement states.

More than one SOCS employee got the NGS list-serv notification about the 16-minute requirement, but NYAMS didn’t hear about it from SOCS, according to the settlement.

Commercial Insurer Rejected Claims

In January 2015, a commercial insurer rejected one of NYAMS’s claims for moderate sedation billed to 99144. A SOCS employee wrote in an internal communication that the “Medicare 16 minute span rule to bill [the] code” wasn’t met, the settlement said. “NYAMS asserts that SOCS did not share this information with NYAMS.”

About five months later, the insurer rejected some claims for CPT code 99144 “where it did not find documentation to support that the procedure lasted more than 16 minutes,” the settlement states. SOCS told NYAMS about the audit and suggested the physicians “review the 99144 findings,” but NYAMS denies this happened, the settlement states.

The settlement also says that NYAMS submitted claims that didn’t comply with local coverage determinations 35336 and 35936 from Dec. 16, 2014, through Jan. 5, 2016. The LCDs allow billing for 99144 “with intraarticular facet joint injections and medial branch blocks only where the medical necessity of sedation was unequivocal and clearly documented,” the settlement notes. NYAMS “identified and voluntarily disclosed this issue to the [U.S. attorney’s office] after NYAMS’s internal review of the time-based aspect of the code in response to the government’s investigation.”

The settlement notes that NYAMS’s conduct only concerns the 16-minute rule and the LCD compliance issue, “not whether the service was rendered or was medically necessary.”

In a statement, NYAMS said, “The agreement is not an admission of liability, misconduct or fraudulent activity of any kind. All patients received the treatments for which billing occurred, and the quality of the care was the same regardless of the length of time of treatment.”

However, the settlement says that “NYAMS does not contest that the Covered Conduct occurred.”

NYAMS billed Medicare, Medicaid, TRICARE and the federal employee health benefit program.

Codes, Descriptors Change in 2017

The codes to report moderate sedation include three components: preservice work, intraservice work, and postservice work. Only the intraservice work, however, which is based on time, can be counted to determine the assignment of CPT codes, Salwin says. According to the CPT code book, intraservice time “begins with the

administration of the sedation agent(s), requires continuous face-to-face attendance, and ends when the personal face-to-face time ends with the patient.”

Big changes came to moderate sedation (conscious sedation) in 2017, when the AMA created new codes, descriptions and guidelines, Salwin says. “Regardless, the one aspect of coding moderate sedation that has stayed the same is documenting time,” she notes.

The description in the CPT code book was slightly modified: “Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient’s level of consciousness and physiological status.”

Documentation Must Mirror Terminology

More significantly, the time unit requirement was changed to a more standard 15 minutes per unit, Blake says. CPT code 99151 is used to report the initial 15 minutes of intraservice time in a patient younger than 5 years of age, and 99152 is used to report the initial 15 minutes of intraservice time in a patient 5 years of age and older, he says. Each additional 15 minutes of intraservice time is reported with 99153 (and listed separately in addition to the code for primary service). According to CPT guidelines, the minimum intraservice (face-to-face) time for moderate sedation is 10 minutes; anything less than that is not reported, he says. “Normally when you exceed the ‘halfway point’ for reporting time, you can report the service, so for a 15-minute unit, you can report one unit if 8 minutes is documented—except for moderate sedation,” Blake says. “This is an important distinction.”

Also new in 2017: there are different codes for moderate sedation performed by a different provider than the one providing the diagnostic or therapeutic service (99155, 99156).

The documentation must mirror CPT terminology, Salwin says. Using terms like “total time spent” or “encounter time was” will not contribute to the time reported for moderate sedation, she says. While pre-sedation and post-sedation work is required, the time spent on them won’t contribute to code selection. “Ideally, your documentation of time should indicate ‘intraservice time was...’”

Contact Salwin at marion.salwin@trinity-health.org and Blake at gblake@deloitte.com. Visit <http://tinyurl.com/ydy9ngg>. ✦

IMM Audits Seem to Ramp Up; Hospital Delivers Form Three Times

After an audit by the quality improvement organization (QIO), Lawrence General Hospital was surprised to learn the Important Message from Medicare (IMM) wasn't in some medical records. Now the Massachusetts hospital isn't taking any chances. To ensure IMMs don't fall through the cracks, inpatients receive the IMM on Mondays, Wednesdays and Fridays.

"It's more than they need, but this is to make sure they get it," says Nicole Garabedian, director of case management for Lawrence General Hospital in Massachusetts.

IMMs are being audited by the QIOs, and it's different than other QIO reviews, such as short-stay reviews under the two-midnight rule. This is an administrative-document audit, not a clinical audit, says Brian Kozik, chief compliance officer. But this is a vivid reminder that when there's a Medicare rule, someone probably is watching. "Every piece of documentation required by Medicare better have an [internal] audit process," he says.

The purpose of the IMM is to explain the patient's right to appeal his or her discharge. CMS requires hospitals to deliver the IMM twice to all Medicare patients – both fee-for-service beneficiaries and Medicare Advantage enrollees. The first time, patients receive it at admission, and the second time, patients must get a copy not more than two days before the date of discharge as a reminder of their appeal rights. Patients appeal their discharge to QIOs, and QIOs are reviewing hospital compliance with these requirements to ensure patients are aware they can appeal their discharges.

Livanta, the QIO for Lawrence General Hospital, requested 10 medical records from the hospital without specifying it was surveilling IMMs. "It wasn't clear the QIO was looking for the IMMs," Garabedian says. "When requests come in for medical records, they're usually for clinical information." As a result, the QIO had findings because it appeared the hospital didn't give IMMs to the patients sampled. Garabedian contacted Livanta and explained the misunderstanding, and the QIO allowed the hospital to submit some of the IMMs, and the audit findings improved.

The QIO acknowledged it wasn't auditing anything substantive about the form, because hospitals are required to use the language in CMS's model IMM. The audit is strictly to determine whether the hospital was delivering the forms to patients at the intervals required by Medicare.

"This should have been an easy win for us, and it wasn't," Kozik says.

The reason the QIO found problems is the two IMMs are stored in different places in the electronic health records (EHRs). "This was a learning opportunity," Garabedian says. After the Livanta audit results came in, she held a meeting with all case managers. They discussed the process and recommendations for improving the delivery of IMMs. As a result, case managers will deliver the IMMs on Mondays, Wednesdays and Fridays, regardless of when the patient's discharge is anticipated. "This process will hopefully ensure that any potential gaps in the delivery of discharge IMMs are closed," she says.

This is the first time in several years that the hospital's IMMs were reviewed by the QIO, she says. Other hospitals are having their IMMs inspected by the QIOs for the first time in a long time (*RMC 7/24/17, p. 3*).

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Former Tenet Executives Indicted

continued from p. 1

"Hitting a corporation in the pocketbook hurts, but you want to prosecute the individuals [allegedly] involved," says former federal prosecutor Scott McBride, with Lowenstein Sandler in Roseland, N.J. "This is a high-profile case and there's a lot of money involved." However, so far almost all the allegations "seem circumstantial," he says.

The three executives allegedly caused Tenet to pay \$12 million in bribes and other unlawful remuneration to Clinica de la Mama to induce the referral of maternity patients who were mostly undocumented Hispanic women. The hospitals benefited from the referrals because Medicaid pays for certain kinds of emergency medical services for undocumented aliens, including emergency labor and delivery and services to newborns. The alleged scheme took place while Tenet was under a corporate integrity agreement (CIA) in connection with a 2006 false claims settlement for alleged kickbacks and upcoding.

To cover their tracks, the executives allegedly created "pretextual contracts," with Tenet paying Clinica de la Mama for marketing consulting, translation services, translation management services, Medicaid eligibility determination paperwork, community outreach, educational classes and birth certificate services, the indictment alleged. In many cases, the services were "(a) not needed and not justifiable; (b) duplicative of services already being provided; (c) substandard or problematic; (d) not rendered at all; and (e)

rendered by persons who were not qualified to perform them,” according to the indictment.

Moore denied the charges, and his attorney, Brian McEvoy, says they’re “extremely disappointed” that the government moved forward with the indictment. “The entire purpose of the contracts was to increase access to pre-natal services for an underserved patient population throughout Atlanta. The contracts were reviewed by counsel and many others inside and outside the company. Bill Moore received no personal benefit and had no intent to violate the law,” says McEvoy, who is with Polsinelli. “Mr. Moore is not guilty and we look forward to presenting this case to a jury at trial.” Holland pleaded not guilty early this year.

Execs Accused of Falsifying Records

The criminal charges stem from Tenet’s 2016 civil settlement and non-prosecution agreement over the kickbacks. Two of the hospitals, Atlanta Medical Center and North Fulton Hospital, which were owned by a Tenet subsidiary, Tenet HealthSystem Medical, pled guilty. The two other hospitals, also owned by the subsidiary, were Spalding Regional Medical Center Inc. in Griffin, Ga., and Hilton Head Hospital in South Carolina. All of the Georgia hospitals in the case have been sold to WellStar Health System.

In the indictment, Holland and Moore are accused of circumventing Tenet’s internal controls and the policies and procedures required by the CIA. For example, Holland and Moore allegedly authorized Tenet payments to Clinica without contracts, adequate supporting documentation, “or proper review and approval.” They tracked the patient referrals to Tenet hospitals—past and present—in logs, emails, spreadsheets, reports and business projects, the indictment alleged.

The three executives also “discussed and analyzed both in emails and meetings the volume of Clinica patients referred to the Tenet Hospitals for medical services related to childbirth,” the indictment alleged.

Other steps were taken to hide the relationship between Tenet and Clinica de la Mama. Holland and Moore allegedly falsified Tenet’s books, records and reports, including internal memos. They also “caused to be submitted cost reports for Tenet Hospitals that contained materially false, fraudulent, and misleading representations that the services identified in the cost report” were compliant with laws and regulations, according to the indictment.

The four Tenet hospitals billed \$400 million to Georgia and South Carolina Medicaid and collected \$149 million in Medicaid and Medicare disproportionate share payments in connection with the Clinica de la Mama patients.

Patients at Clinica de la Mama were affected by the alleged fraud. Some of them were falsely told that Medicaid would only cover their childbirth costs if they delivered at a Tenet hospital. That led patients to believe they couldn’t receive childbirth-related services from a hospital of their choice, the indictment alleged. “Some Clinica patients, as a result of defendants’ intended conduct, traveled long distances from their respective homes to deliver at a Tenet Hospital and bypassed other hospitals to do so, all of which at the very least created a reckless risk of serious personal and bodily injury to the Clinica patients and their respective babies,” according to the indictment.

Lawyer: Indictment Is Vague

There’s no smoking gun in the indictment in terms of the kickback allegations, McBride says. “The allegations and even the overt acts all hinge on whether or not there is an improper kickback arrangement,” he says. “They are all circumstantial, conclusory allegations. They discussed how many patients this clinic was referring to the hospitals. So what? That’s what hospitals do.” Emails are mentioned but not the content, for example. And while the indictment lists a series of payments from Tenet to Cota Medical Management, the subsequent name for Clinica de la Mama, “they’re not at all relevant or meaningful unless the underlying conduct is illegal,” McBride says. The existence of referrals and contracts for services are not enough to infer a quid pro quo, he says. “They’re not alleging it was a sham contract.”

Based on the indictment, prosecutors are either “trying to retain a great level of flexibility in the proof they put forward at trial or plan on proving it circumstantially,” he says. “The only place where they made actual allegations of something approaching fraud...is the nugget of lying to pregnant mothers about where they are allowed to get services in relation to their babies.”

In a nutshell, prosecutors make fraud cases in two steps: (1) the deed was done and (2) how the defendant did it, McBride says. “On the kickback charges, prosecutors don’t really address step two. You still wonder how the defendants violated the anti-kickback statute. They try to answer it by saying the contracts were ‘pretextual,’ but that just begs the same question: how were they pretextual? They do talk about the low quality of the services provided under the contract, but to me, that is subjective and not quite specific enough,” he says.

“I would think they would need more evidence than that to show the contract is a pretext, such as witness accounts of the conversations that went into executing the contracts,” McBride says. Otherwise, prosecutors will have a hard time proving anti-kickback

charges. Jurors are hard to convince in this arena, he says.

Allegedly lying to pregnant women, however, is “fraud on its face,” he says.

“It’s important to note that the government only has to prove that one of the reasons for the contracts was referrals, so that’s an inherent advantage,” McBride says. And “circumstantial evidence is still evidence and sometimes it’s as good as or better than” direct evidence.

The indictment also describes how Tenet’s CIA, which lasted from 2006 to 2012, required the hospital chain to strengthen procedures to ensure its arrangements didn’t violate the anti-kickback law, and for re-

gional and hospital executives to attend arrangements training. Tenet also had to notify the HHS Office of Inspector General of “reportable events” (e.g., probable violations of law) and senior corporate management certified in writing that Tenet was in compliance with the requirements of federal health care programs, to the best of their knowledge. Holland and Moore allegedly made misleading statements on annual reports submitted to OIG under Tenet’s CIA from 2007 to 2012, according to the indictment.

Contact McBride at smcbride@lowenstein.com. Visit <http://tinyurl.com/y6ufkmpm>. ✧

NEWS BRIEFS

◆ **Four Houston-area hospitals have agreed to pay \$8.6 million to settle false claims allegations they received kickbacks from ambulance companies, the U.S. Attorney’s Office for the Southern District of Texas said Oct. 4.** The hospitals—Bayshore Medical Center, Clear Lake Regional Medical Center, West Houston Medical Center and East Houston Regional Medical Center—are affiliated with Nashville-based Hospital Corporation of America. The U.S. attorney’s office alleged they engaged in swapping arrangements with the ambulance companies. “The settlement announced today resolves allegations that patients at the four hospitals received free or heavily discounted ambulance transports from various ambulance companies in exchange for the hospitals’ referral of other lucrative Medicare and Medicaid business to those same companies. If not for this kickback arrangement, the four hospitals would have been financially responsible for the patient transports at significantly higher rates,” the U.S. attorney’s office said. The case was set in motion by three whistleblowers who filed two false claims lawsuits. The hospitals didn’t admit liability in the settlement. Visit <http://tinyurl.com/yc86t5jx>.

◆ **CMS has rescinded an MLN Matters (SE17023) that cautioned Part B providers to put the correct dates of service on their claims, with an emphasis on when the service is completed as opposed to when it begins (RMC 9/25/17, p. 1).** CMS offered no explanation for the rescission of the Sept. 19 MLN Matters but said it may be re-issued. Visit <http://tinyurl.com/yalvwemd>.

◆ **The HHS Office for Civil Rights on Oct. 3 clarified the parameters of disclosures to family friends and other people involved in patient care under the HIPAA Privacy Rule in light of the mass shooting in Las Vegas.** “A HIPAA covered entity may share protected health information with a patient’s family members, relatives, friends, or other persons identified by the patient as involved in the patient’s care. A covered entity also may share information about a patient as necessary to identify, locate, and notify family members, guardians, or anyone else responsible for the patient’s care, of the patient’s location, general condition, or death. This may include, where necessary to notify family members and others, the police, the press, or the public at large. See 45 CFR 164.510(b).” For answers to frequently asked questions on notifications, visit <http://tinyurl.com/yawn5hz6>.

◆ **Cybersecurity is important to Americans — so important that 42% would be willing to give up alcohol, 30% would be willing to give up social media, and 29% would be willing to give up chocolate to ensure their personal data is never leaked, according to a survey from IT and engineering firm Modis.** Those surveyed view their credit card and Social Security information as the most sensitive, with taxes and medical history coming in third and fourth. Still, more than two-thirds said they wouldn’t pay anything to get their data back if it was hacked. View the survey results at <http://bit.ly/2xLUJme>.