Report on
Medicare Compliance

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

Contents

Former Tenet Executive Charged with Fraud; Compliance Attestations at Heart of Case

Prosecutors have drawn a line from promises that a hospital executive purportedly broke when he signed compliance attestations while allegedly arranging payments for referrals to an indictment for fraud.

John Holland, former senior vice president of operations for Tenet Healthcare Corp.'s southern states region and CEO of North Fulton Medical Center Inc. in Roswell, Ga., was charged with mail fraud, health fraud and major fraud in connection with the kickback scheme for maternity patients that led to Tenet's $513 settlement and non-prosecution agreement in October 2016 (*RMC 10/17/16, p. 1*), the Department of Justice said Feb. 1. However, the indictment is short on specifics, attorneys say. "It looks like a difficult case for the government to prove," says former federal prosecutor Scott McBride, with Lowenstein Sandler in Roseland, N.J.

That impression is shared by former federal prosecutor Robert Trusiak. "This is a very broad set of allegations stated generally in a conclusory manner without detail," says Trusiak, with Health Care Compliance Support in Buffalo, N.Y. Presumably the details will spill out during discovery and other pretrial maneuvering. The criminal case

continued on p. 6

Compliance Is Often Stuck in Checkbox Mentality; 'Strategic Value' Has More Impact

When former compliance officer Steve Ortquist meets with senior executives and board members about their organization's compliance program, he's surprised to find they can't always put their finger on what it's all about. They may give a vague reason for the compliance program, like "to make sure we're in compliance," or a single-minded reason, like keeping people out of jail.

"Something is wrong," said Ortquist, managing director of the Aegis Compliance and Ethics Center in Phoenix. "I regularly don't see organizations rallying around a larger purpose. They are checking the box — doing something they think they have to do — without a larger understanding or vision for what they're doing." It could make an enormous difference for the compliance program and the organization as a whole if senior leaders and board members see its strategic value. "Maybe we as compliance people need to start having a conversation that forces people to start thinking about this," Ortquist said on a Feb. 6 webinar sponsored by the Health Care Compliance Association. "If you can get to that place where an organization's leadership and board see [compliance] processes as integral to the overall organizational strategy, it can really transform what happens in this arena." That will require being far more concrete — establishing goals, measuring progress and reporting results in dashboards.

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HEALTH CARE COMPLIANCE ASSOCIATION

Managing Editor
Nina Youngstrom
Nina.Youngstrom@hcca-info.org

"The overarching premise is that what leaders really engage in actively is something that they see as a strategic benefit," he noted. "The strategic value of the compliance program may be different and less in some ways than the strategic value of a merger or building a new revenue stream, but if they can see the compliance program as being strategic, not just something you have to do," it will be more effective. When the compliance program takes a structured approach to evaluating risk and develops a work plan based on that instead of firing at every target, "and the leadership team can see this, I think they will be more likely to engage with it."

In fact, compliance officers will be more effective in the context of strategic initiatives if they focus on three areas: Stark and the anti-kickback law; revenue cycle/coding and billing and privacy and security. "These are not the only areas. For example, in the hospital setting, you also think of the [Emergency Medical Treatment and Labor Act]," Ortquist said (*RMC 1/30/17, p. 1*). "But if you look at a mature program, it's focused on these three bubbles."

He suggested compliance officers get the compliance committee and board more involved in the process of developing the risk assessment and the work plan, and provide them with dashboards that vividly show what the compliance program has accomplished. "If those two bodies are functioning the way they need to, they are really going to be instrumental in driving the compliance program strategically," Ortquist said. But the executive compliance committee is more hands on than the board's audit/compliance committee.

The compliance committee should be made up of top executives rather than midlevel managers "who aren't at a level where they can drive the program forward in a more strategic way," he said. The executive compliance committee "will be a group that has the reporting relationships and the chutzpah to drive things in the way they need to be driven," Ortquist said. For example, the executives on the committee have the clout to get compensation tied to compliance outcomes "or, if you're dealing with a problem that requires interaction with the medical staff, to get from where you are to where you need to be, that executive level committee will have the right relationships and positions to move them forward." A subcommittee of midlevel managers will be useful to ensure compliance on a day-to-day basis, he noted.

There are different expectations of the board's audit/compliance committee, a fact that's been driven home

Thinking Through Compliance Strategy

This chart is designed to help the compliance officer, management, the board and the compliance committee have a conversation about who will be involved in the various tasks of compliance, said Steve Ortquist, managing director of Aegis Compliance & Ethics Center. "The compliance officer's job is to manage and implement the compliance program, not to ensure the organization is in compliance," he said. Contact him at sortquist@aegis-compliance.com.

	Compliance Officer	Executive Compliance Committee	Board of Directors	Management	Legal Counsel
Assuring Compliance					
Managing Compliance Program					
Implementing Compliance Program					
Setting Tone and Culture					
Setting Compliance Program Strategy					
Providing Oversight					
Providing Resources					
Conducting Investigations					
Corrective Action Implementation					

in recent corporate integrity agreements. In terms of the compliance attestations that board members and executives must sign in the CIAs, "at both levels they have to have a significant understanding of the risks and processes and that you are going after this risk or that, but there is more personal responsibility for the state of compliance at the management level than the board." At the same time, compliance officers should hash out who will be responsible for various compliance tasks with the executive compliance committee, board members, managers and others (see box, p. 2).

Information sharing is also key to promoting compliance in a broader context. "How do you give the board and committee enough so they establish a strategy and have a good sense of what kinds of allegations are made to the hotline and what kind of performance the compliance program has?" The packet should be "meaty," he said, but there is an argument to be made for not overwhelming the board. "I always tried to include some education piece about a compliance risk area in every quarterly board report."

Leaders are also more invested when they see dashboards that show measurable results in core compliance-program operations. "The more you can measure what you are trying to achieve and demonstrate that to your board, the better off you are," he said. Examples of metrics: the number of people who were assigned Stark training and completed it; the average number of days it takes to close an investigation; the percentage of inpatient admissions without signed orders before discharge; the number of physician contracts that were executed without legal review and the number of payments to physicians for certain arrangements (e.g., medical directorships, on-call services, leases) without the necessary approvals.

Contact Ortquist at sortquist@aegis-compliance.com.✧

With MOON Deadline Around Corner, Consider Other Notices As Well

All eyes are on the Medicare Outpatient Observation Notice (MOON), which takes effect March 8, and compliance may be trickier than anticipated. Hospitals may find it useful to approach compliance with the MOON, which informs patients they are outpatients receiving observation services, not inpatients, in tandem with other patient notices, including the advance beneficiary notice (ABN) and Hospital-Issued Notice of Non-Coverage (HINN).

CMS posted the final MOON on its website on Dec. 8 (*RMC 12/12/16, p. 1*). It created the form in response to the Notice of Observation Treatment and Implication for Care Eligibility (NOTICE) Act, which was signed by President Obama on Aug. 6, 2015. According to the NOTICE Act, hospitals are required to notify patients who receive 24 hours or more of observation services that they are not inpatients within 36 hours after physicians have written the observation order. The MOON tells patients that, "You're a hospital outpatient receiving observation services. You are not an inpatient because:" followed by a blank space, where physicians or other hospital staff will have to explain why. In instructions posted with the MOON, CMS said, "Fill in the specific reason the patient is in an outpatient, rather than an inpatient stay." On Jan. 20, CMS issued Medicare Transmittal 3695 to explain a bit more how to administer the MOON (*RMC 1/30/17, p. 8*).

MOON May Go Down Easy

It's always possible the MOON will go down easy. "Lot of patients will just sign the MOON," said Ronald Hirsch, M.D., vice president of R1 Physician Advisory Services, at a Feb. 2 webinar sponsored by RACMonitor.com. Even if they have questions, patients can sign the MOON, as long as they get answers within the 36-hour statutory deadline. "There's no requirement to show all their questions have been answered when they sign the

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form. It's a nice time to do it in the beginning" of observation.

Getting this far with the MOON has taken a while. CMS fleshed out the law in the proposed 2017 Inpatient Prospective Payment System (IPPS) regulation released April 18 (*RMC 4/25/16, p. 1*) and proposed the MOON a week later (*RMC 5/2/16, p. 6*). Then CMS revised the MOON in the final IPPS regulation and posted a draft on Aug. 1 (*RMC 8/8/16, p. 1, 6*). It got the green light from the Office of Management and Budget (OMB) under the Paperwork Reduction Act on Dec. 7.

Hospitals can't modify what's already in the MOON (e.g., wording, font size) or reorganize sections because it's PRA approved, although they can add to it. If you use preprinted chart labels, make sure they don't cover over important Medicare words, Hirsch said.

The Less Said, the Better?

There's been a lot of debate about the blank space where hospitals will explain why patients are not inpatients, which invariably irritates them for various reasons (e.g., outpatient days don't help patients quality for admission to skilled nursing facilities). "We have no clue what CMS really wants. We have no official guidance," Hirsch said. He has repeatedly asked whether it's OK to use checkboxes, but CMS has not said "yes" or "no," so "I am taking it to mean if they prohibited checkboxes we would have heard by now."

His suggestions for checkboxes are:

- □ Your doctor expects that you will need hospital care for less than a total of two days.
- □ You require more care after your surgery but should be able to be discharged within a total of two days.
- □ Your Medicare Advantage plan has told your doctor to place you in Observation.
- □ Other:

The explanation should be brief and just mention the two-midnight rule when appropriate, which is what the first checkbox alludes to, Hirsch said. There's no way checkboxes could be more specific because there are dozens of conditions that could account for a medical observation stay (e.g., chest pain, asthma). "My philosophy is, give patients as little information as they need, which is they don't meet the two-midnight rule," Hirsch contended. "They don't need a clinical reason why" – e.g. your potassium is mildly low – "and the physician doesn't need to document it."

Patients must sign, date and time the MOON, but if they refuse, hospitals just have to document their refusal to sign in the additional information section, Hirsch said. Don't forget that the MOON must be given orally. If patients are legally incompetent to sign the MOON, an authorized representative may sign it. CMS explains this in detail in the transmittal. If they're temporarily unable to receive it (e.g., they're on pain medication), delivery should be delayed.

What happens when patients are admitted as inpatients after 24 hours? "You still must give them the MOON," he said, but note the time and date of the admission. It's another reason why Hirsch advised giving patients the MOON on the early side. Even though CMS encouraged hospitals in the IPPS regulation not to give patients the MOON before 24 hours have elapsed, encouragement is not a statutory obligation, Hirsch noted.

However, when Medicare Advantage patients deny admissions and tell the hospital to bill the whole stay as observation, Hirsch doesn't think the MOON is necessary. "The order in the chart is for inpatient," he said. "They may bill as observation but the patient didn't receive observation as a service."

The MOON, of course, is not the only patient notification form that hospitals have to worry about. "The MOON and ABN are partners in notifying outpatients of their rights and liability and the Important Message from Medicare and the HINNs partner to notify inpatients of their rights and liability," Hirsch said.

When patients have received the MOON and finish receiving care, but are reluctant to leave, what should hospitals do? "They get an ABN," he says. The hospital asks them to sign a form accepting financial responsibility for services that Medicare would not consider a medical necessity, which in this case would be observation. CMS requires certain information on the form, including the services provided (i.e., nursing services), the reason why Medicare may not pay and the estimated cost. "Go to the finance people and ask what you charge for G0378," which is one hour of observation services.

If the patient has no medically necessary reason to stay in observation but the physician signed an admission order, hospitals use the preadmission HINN, Hirsch said. "We are notifying the patient that Medicare won't pay for that admission" even if the doctor is insisting on admitting the person, he explained. "It's also helpful for patients who insist on admission to get the three-day stay and then go off to the SNF. It often happens with family who are worn out caring for a loved one and heard if patients get admitted for three days, they can get into a SNF. We can bring them into the hospital and do everything we can to find an alternative discharge plan, but if we can't, sometimes it's worth getting a preadmission HINN, asking the physician to write an admission order like the family wants and then asking the family to call the QIO to file an appeal." Once in a while, the QIO will approve the inpatient admission, Hirsch said.

Also, if physicians don't want to discharge patients but the hospital believes they are stable, it can issue a HINN 10. "That's a hospital-requested review," Hirsch said. "It's given to the patient as a courtesy. More importantly, it goes to the QIO, which steps in for the physician to decide whether the patient is stable."

It's also important to understand the HINN 11, which is used when patients have a medically necessary reason to be an inpatient, but the physician has ordered a test or procedure that's not medically necessary (e.g., automatic implantable cardiac defibrillator on a patient who doesn't qualify according to the Medicare national coverage determination). "Talk to the doctor first to see if they can justify the procedure if they document better," Hirsch said. Otherwise, liability is shifted to the patient through HINN 11 unless the test or procedure is done on an outpatient basis.

Contact Hirsch at rhirsch@r1rcm.com. CMS has set up a mailbox for MOON questions at moonmailbox@cms.hhs.gov .✧

Payment Rules Are Exempt from One In, Two Out Exec Order, With Limits

Medicare regulations may be less affected by President Donald Trump's Jan. 30 executive order than originally expected, after it was clarified by Feb. 2 interim guidance. The executive order, which said two regulations must be ditched for every new one introduced, offers both the promise of relief from some exacting Medicare requirements and the loss of a channel to negotiate them with CMS, attorneys say.

The executive order states that: "Unless prohibited by law, whenever an executive department or agency... publicly proposes for notice and comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed." The goal of the executive order is to ensure the cost of new regulations is offset by eliminating existing regulations, and it includes rules that weren't finalized before noon on Jan. 20, 2017.

Some of the impact of the one in, two out executive order has been mellowed by the guidance. For example, the guidance exempts Medicare payment regulations. Also, the executive order only applies to "significant regulatory actions, as defined in Section 3(f) of Executive Order 12866, an agency issues between noon on January 20 and September 30, 2017." That refers to a 1993 executive order, which defined "significant" as regulations costing $100 million or more.

Between the exemption for payment regulations and the clarification that one in, two out only applies to regulations costing $100 million or more, "Medicare may well find that it can continue to do business as usual," says Washington, D.C., attorney Andy Ruskin, with Morgan Lewis. "It has gone from something that looked like it would bring the government to a halt to something that could help the provider." If they are "miffed" about a proposed regulation and the regulatory impact exceeds $100 million, Ruskin says providers should challenge CMS's authority to promulgate it unless two other regulatory burdens are removed.

Boston attorney Larry Vernaglia believes the exemption for payment rules may be limited to rules that "cause income transfers from taxpayers to program beneficiaries," as the guidance states, but it also notes that "in cases where these rules impose requirements on non-Federal entities, such as reporting or recordkeeping, agencies would need to account for these costs." In other words, HHS has to remove costs to cover new regulatory costs even if they arise from a payment rule, says Vernaglia, with Foley & Lardner LLP.

Rules Based on Laws are Trickier

It won't be that easy to ditch some regulations when they come from laws, Vernaglia says. "When you have regulations that seem to be mandated by statute, you probably won't get a lot of traction on eliminating the entire regulation," he says. "You might want to recommend leaving some shadow of the former regulation in its place." Examples include the Stark law and the Medicare Access and CHIP Reauthorization Act (MACRA). "Stark is expensive and duplicative of the anti-kickback statute, so no beneficiary would be harmed and it would save a lot of money, but there is a statute there, so something would have to survive – maybe just the statute itself," Vernaglia says. Unfortunately, he adds, Stark also could be characterized as a payment rule, "so future additions may be exempt from requiring a deregulatory action." He also thinks a lot of providers would rejoice if HHS did away with big chunks of the HIPAA privacy and security regulations. "No one would ever miss it at the annual party of regulations," Vernaglia says. The "hard part," however, is "there are always people who love each of these regulations."

Because some laws are embraced by the industry, it won't want the regulations held up, says Sarah Thomas, managing director of the Center for Health Solutions at Deloitte & Touche. "If I were the HHS Secretary, I'd figure out a way to implement them and not get in the way of my own goals," she says. One example is the 21st Century Cures Act, which speeds drug and device approvals and created a mid-build exception for off-campus provider-based departments that were otherwise barred from billing the outpatient prospective payment system if they were established on or after Nov. 2, 2015 (*RMC 1/9/17, p. 1; 12/5/16, p. 3*). "I would think the industry

would be eager to see these provisions that would fulfill that process," Thomas says.

It's still unclear how much flexibility there is with the one in, two-out executive order, Thomas says. "Maybe parts of regulations can be traded for other parts of regulations or the reduction can come by simplifying forms and processes," which is what regulators did in the United Kingdom's 2005 to 2009 one in, one out regulatory swap, according to Jitinder Kohli, managing director with Deloitte Consulting, who wrote about it in *Forbes* magazine.

Vernaglia sees the one in, two out executive order as an opportunity for compliance officers to "reshape" their functions. If some rules were narrowed or killed, compliance officers could move the furniture around, opening up room for more "productive" initiatives. "If you could focus on quality of care and actual waste and abuse, like double billing and services not provided, it would be better," Vernaglia says. One example: eliminating the distinction between inpatient vs. outpatient status because auditors and compliance officers could instead focus on areas like medically unnecessary spine surgery, he says.

For now, though, it's as you were, Thomas says. "There's not much you can do until the regulations change," Thomas says. "Continue to comply with laws and other guidance consistent with your program until specific guidance comes out. It's too general to begin to imagine scenarios." Although she also advises compliance offices to keep an eye on what their trade associations are putting on their wish lists for regulations to eliminate.

Contact Vernaglia at lvernaglia@foley.com, Ruskin at aruskin@morganlewis.com and Thomas at sarthomas@deloitte.com. View the interim guidance on the executive order at http://tinyurl.com/joluauh.✧

CMS Transmittals

Jan. 27 — Feb. 9

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

Transmittals

(R) indicates a replacement transmittal.

Pub. 100-20, One-Time Notification

- Instructions to Hospitals on the Election of a Medicare-Supplemental Security Income (SSI) Component of the Disproportionate Share (DSH) Payment Adjustment for Cost Reports that Involve SSI Ratios for Fiscal Year (FY) 2004 and earlier, or SSI Ratios for Hospital Cost-reporting Periods for Patient Discharges Occurring before October 1, 2004, Trans. 1776 (Jan. 27, 2017)
- Updated Editing of Professional Therapy Services, Trans. 1775 (Jan. 27, 2017)
- Change to Beneficiary Liability and Cost Report Days for Subclause (II) Long Term Care Hospitals (LTCHs), Trans. 1791 (Feb. 3, 2017)
- Payment for Oxygen Volume Adjustments and Portable Oxygen Equipment- FISS, Trans. 1785 (Feb. 3, 2017)

Pub. 100-04, Medicare Claims Processing Manual

- Implementation of New Influenza Virus Vaccine Code, Trans. 3711 (Feb. 3, 2017)
- Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) Edits, Version 23.1, Effective April 1, 2017, Trans. 3708 (Feb. 3, 2017)
- New "K" Code for Continuous Positive Airway Pressure Device Bundle, Trans. 3710 (Feb. 3, 2017)
- Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - April 2017, Trans. 3702 (Feb. 3, 2017)
- Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits, Trans. 3701 (Feb. 3, 2017)

Former Executive is Indicted

continued from p. 1

doesn't seem like an exercise of the Yates memo, also known as the Individual Accountability Policy, which requires prosecutors to pursue "culpable" individuals in corporate fraud cases (*RMC 10/3/16, p. 1*), Trusiak says. The allegations have more to do with DOJ's attempt to hold Holland accountable for allegedly lying on the compliance attestation, Trusiak contends.

The indictment echoes the paperwork filed when Tenet entered into its global resolution, which included a guilty plea by Atlanta Medical Center and North Fulton Hospital, two Atlanta-area hospitals owned by a Tenet subsidiary, Tenet HealthSystem Medical, as well as a false claims settlement by the two hospitals and two others owned by the subsidiary, 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.

The case centered on contracts between the Tenet hospitals and clinics owned by Clinica (also known as Clinica de la Mama). On paper, Tenet paid the clinics for management services, marketing consulting services, translation services, translation management services, Medicaid eligibility determination paperwork, community outreach, educational classes and birth certificate services, but this was allegedly a ruse to induce the referrals of clinic patients, according to the government.

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. However, the services were, in some cases, not necessary, duplicative, substandard or not provided. The scheme took place while Tenet was under a CIA in connection with a 2006 false claims settlement for alleged kickbacks and upcoding.

As a top executive, Holland allegedly greased the wheels, according to the indictment. "John Holland and his co-conspirators created and caused to be created pretextual contracts between the Tenet Hospitals and Clinica," the indictment alleges. They "circumvented" internal controls and CIA policies and procedures by green-lighting payments to Clinica without valid contracts, supporting documentation or appropriate reviews "with the purpose of inducing Clinica to refer the Clinica patients to the Tenet Hospitals and to arrange for services to be provided to the Clinica patients at the Tenet Hospitals."

To cover up the nature of the Clinica relationship, Holland and his co-conspirators allegedly dummied books and reports. They also made misleading statements in internal Tenet memos, the indictment alleges. The government alleges that Tenet received $149 million from Medicaid and Medicare because of the illicit patient referrals.

Indictment: OIG Relied on Attestation

During some of this time, Tenet's five-year CIA required senior corporate managers to submit annual reports to certify in writing that as far as they knew, they were in compliance with laws and regulations. To fulfill this requirement, Tenet set up a process for its regional and hospital executives to "accurately and honestly" complete the attestations and report any material violations, according to the Holland indictment. "These certifications were relied upon by Senior Corporate Management, the Chief Compliance Officer, and Regional Compliance Officers to certify to HHS-OIG that Tenet was in compliance with Federal health care program requirements and the obligations under the CIA," the indictment alleges. Holland signed these attestations from 2007 to 2012, and OIG relied on his pledges and the annual reports to evaluate whether the hospital chain fulfilled its CIA obligations, the indictment says.

Holland's indictment isn't an expression of the Yates memo as much as it's the government seeking penalties for CIA violations when its other recourse – kicking the hospitals out of federal health care programs – isn't viable because that would hurt the community, Trusiak says. So DOJ circled back to a top executive who signed compliance certifications that were submitted to OIG, he says. "The indictment has nothing to do with the Yates memo and it has everything to do with the fact that the only other thing the government could do was exclude the hospitals and it would never do that," Trusiak says. "So yes, it's about individual culpability, but it has nothing to do with the Yates memo."

But Trusiak and McBride were struck by how vague the indictment is. "I thought there would be more in the indictment," McBride says. "Other than the defendant filling out boilerplate certifications, they didn't link him directly to contracts or payments. I was surprised there was not some type of example."

It's hard enough to convince a jury to convict in kickback cases when there's cash in an envelope, McBride says. That means the government will have to bring its "A" game if it wants to put Holland in jail and forfeit his assets in a case where there are no allegations that pregnant women were harmed. "Jurors don't always initially understand why this behavior is criminal, and if you have a hospital that's presumably providing services to poor undocumented pregnant women, and there's no issue with the standard of care these women received," it may be up uphill battle for prosecutors, he says. "The defendant's lawyer will hammer at the amorphous allegations unless the government has actual examples of direct and willful conduct," McBride predicts.

When he drafted indictments, Trusiak says he "tried to give himself as much room as possible," but there is an unusual amount of space in the Holland indictment. For example, alleging that Tenet is tracking referrals is one thing, "but tying referrals to bribes is another," he says. The indictment doesn't even touch on lack of medical necessity, Trusiak notes.

Escobar Might Be in Play

The landmark U.S. Supreme Court decision in *United States ex rel. Escobar v. United Health Services* may also figure into the Holland case (*RMC 6/20/16, p. 1; 9/26/16, p. 1*). Prosecutors contend that Holland's alleged false compliance certification allowed the hospitals to continue their Medicare participation, but that may not fly in the wake of the Escobar "implied certification" decision, Trusiak says. The Supreme Court in June 2016 ruled that not every regulatory violation amounts to a condition of payment and therefore a potential false claim; a violation has to be "material" enough to have affected payment. In the Holland case, the defense may argue the compliance certifications were not material to government payment decisions, he says.

Holland has pleaded not guilty. His attorney, Richard Deane, did not respond to RMC's request for comment.

Contact McBride at smcbride@lowenstein.com and Trusiak at Robert@trusiaklaw.com. ✧

NEWS BRIEFS

◆ **A former Department of Justice attorney who worked on Medicare false claims lawsuits was arrested Jan. 31 for allegedly trying to sell sealed documents in a whistleblower case to the company that was the target of the lawsuit,** according to the *New York Times*. Attorney Jeffrey Wertkin, who had taken a job with the law firm Akin Gump Strauss Hauer & Feld in Washington, D.C., was arrested in California in an FBI sting after the technology security company he allegedly tried to sell the documents to contacted the government.

◆ **Kaiser Foundation Health System has paid $850,000 to resolve allegations over violations of the Controlled Substances Act (CSA),** the U.S. Attorney's Office for the Eastern District of California said Feb. 9. The government alleged that a Kaiser Permanente pharmacy in Modesto improperly filled defective prescriptions and didn't keep accurate records. A lot of the prescriptions filled by the pharmacy allegedly were incomplete, the U.S. attorney's office said. They allegedly didn't have patient and dosage information, which is required by the CSA. Also, the pharmacy allegedly didn't keep correct documentation of incoming and outgoing controlled substances. Visit http://tinyurl.com/z8mah39.

◆ **A Fort Myers, Fla., urologist agreed to pay $3.81 million to settle false claims allegations in connection with billing for lab tests that weren't medically necessary,** the U.S. Attorney's Office for the Middle District of Florida said Feb 1. At the time of the alleged misconduct, Meir Daller, M.D., practiced at Gulfstream Urology, a division of 21st Century Oncology, LLC, which provides integrated cancer care services nationally. The false claims lawsuit, which was originally filed by a whistleblower, alleged that Daller billed Medicare and TRICARE for fluorescence in situ hybridization (FISH) tests that weren't medically necessary, the U.S. attorney's office said. FISH tests, which are performed on urine samples, can detect genetic abnormalities associated with bladder cancer. Starting in 2009, Daller referred all FISH testing to a lab owned by 21st Century Oncology, and he ordered more than 13,000 tests on Medicare patients, "making him the number one referring physician in the country with respect to FISH tests," the U.S. attorney's office said. 21st Century Oncology paid the urologist $2 million in bonuses partly because of the volume of lab tests he referred. In an unrelated case, 21st Century Oncology and its subsidiary, South Florida Radiation Oncology LLC, paid $34.69 million last year to settle false claims allegations over claims they submitted for an oncology procedure that allegedly wasn't medically necessary or was performed by physicians without the proper training (*RMC 3/14/16, p. 6*). Visit http://tinyurl.com/jnoyku2.

◆ **Long-awaited omnibus guidance on the 340B drug-discount program apparently will not materialize.** The HHS Health Resources and Services Administration (HRSA) has withdrawn the guidance, also known as the mega-reg, from regulatory review by the Office of Management and Budget. The proposed omnibus guidance narrowed the definition of "eligible patient," among other things (*RMC 9/7/15, p. 1*). View https://www.reginfo.gov/public/do/eoDetails?rrid=126712.

◆ **TeamHealth Holdings, as successor in interest to IPC Healthcare Inc., has agreed to pay $60 million to settle false claims allegations stemming from upcoding by its hospitalists,** the Department of Justice said Feb. 6. IPC Healthcare, formerly known as IPC The Hospitalists Inc., allegedly overcharged Medicare, Medicaid, the Defense Health Agency and the Federal Employees Health Benefits Program. DOJ alleged that IPC "knowingly and systematically encouraged false billings by its hospitalists," who take care of hospitalized patients. The lawsuit was originally filed by Bijan Oughatiyan, a physician and former IPC hospitalist. According to the lawsuit, "IPC encourages its hospitalists to maximize their billings through peer pressure and ranking hospitalists against each other," and they "have no incentive to use appropriate billing codes" because management "looks the other way," DOJ alleged (*RMC 6/23/14, p. 4*). For example, at the time one hospitalist joined IPC in July 2007, she billed 71.4% of her claims for subsequent hospital care at the lowest level of evaluation and management services (CPT code 99231), the rest at the middle level (99232) and none at the highest level (99233), the complaint alleged. After a few months with IPC, no subsequent hospital care visits were billed at the lowest level of E/M service, almost 59% were billed at the middle level and 41.2% were billed at the highest level. "By 2008, [the hospitalist] had been fully indoctrinated into IPC's scheme," with 100% of her claims for subsequent hospital care billed at the highest E/M level of service, DOJ alleged. Visit http://tinyurl.com/z5b4pdb.