New OIG Guidance on Board Oversight Could Be a Compliance Game Changer

Compliance programs may get more traction with the release of new guidance on compliance oversight for health care board members. The guidance, which was unveiled April 20 by HHS Inspector General Daniel Levinson at the Health Care Compliance Association’s Compliance Institute in Orlando, sets forth a more activist role for boards in their organization’s compliance with laws and regulations. That includes holding managers accountable for compliance, supporting the self-disclosure of “compliance failures” and having regular executive sessions with compliance officers to “encourage more open communication.”

Boards should “develop a formal plan to stay abreast of the ever-changing regulatory landscape and operating environment,” according to the guidance, which OIG developed with HCCA, the American Health Lawyers Association and the Association of Healthcare Internal Auditors. Board members need reports on compliance and risk mitigation “separately and independently” from audit, compliance, human resources, legal, quality, and information technology so they can ask management “more pertinent questions” and “make informed strategic decisions about compliance.”

The message from OIG and its industry partners is clear: “The board of directors is part of the compliance team,” says former federal prosecutor Robert Trusiak, who is now a principal in Compliance Experts, LLC, in Buffalo, N.Y. “It sets a new bar by investing those with the fiduciary commitment to the hospital — the board — in compliance in an affirmative manner rather than through passive oversight.” This could be continued on p. 6

Hospital Settles Stark Case Over Bonuses To ER Physicians, Cardiology Compensation

A Texas hospital agreed to pay $21.75 million to settle false claims allegations that it gave bonuses to emergency room physicians for their patient referrals to a cardiac unit and overpaid employed cardiologists in violation of the Stark law, the Department of Justice and U.S. Attorney’s Office for the Southern District of Texas said on April 21. Citizens Medical Center, a county-owned hospital in Victoria, was sued by three whistleblowers — cardiologists who said they lost access to their patients when the alleged scheme was set in motion — and the government eventually intervened in part of the lawsuit to effectuate a settlement.

In the complaint, the three whistleblowers tell the story of how their professional lives changed when Citizens Medical Center implemented new financial arrangements with other physicians. Until 2007, Dakshesh “Kumar” Parikh, M.D., Harish Chandra, M.D., and Ajay Gaalla, M.D., who are board certified in interventional cardiology and cardiovascular diseases, regularly admitted patients to the hospital and treated them there. The hospital then started paying quarterly bonuses to ER physicians for referring chest-pain patients to its Chest Pain Center. Even when patients “had established
relationships with the [whistleblower-physicians]” and requested their services, they were sent to the Chest Pain Center instead, the complaint said. “In exchange for the bonus payments, the ER Physicians have referred many Medicare and Medicaid patients to CMC’s Chest Pain Center for which the Government has paid reimbursement,” the complaint alleged.

The bonuses allegedly took into account the volume and value of the ER physicians’ referrals in violation of the Stark law. According to the complaint, revenue from the Chest Pain Center was split in half with the referring ER physicians. For example, from Sept. 16, 2008, to March 18, 2010, the hospital allegedly paid the ER physicians $647,049 in bonuses for patient referrals, and another $190,665 from March 18, 2010, to July 22, 2010.

The settlement confirms that ER physicians can be a vehicle for alleged Stark violations, says attorney Bob Wade, who is with Krieg DeVault in Mishawaka, Ind. Although the Stark law exempts only three types of physicians — pathologists, radiation oncologists and radiologists with respect to diagnostic tests — people also try to exclude ER doctors and anesthesiologists in the hospital, he says. They aren’t perceived as having power over referrals, but Wade says there is a distinction between the two. “ER doctors do refer, while there is a strong argument anesthesiologists do not refer because what they do does not impact the DRG billed unless they are performing pain management services,” he explains.

Wade is surprised the Department of Justice didn’t intervene until the end of the Citizens Medical Center case because the allegations draw a direct line between the bonus pool and the patient referrals. “The pinnacle issue in this case is the fact that compensation paid to ER physicians was directly linked to the volume or value of referrals to the Chest Pain Center,” he says. That’s far less subtle than the allegations in the Stark case against Halifax Health, which ended with the Daytona Beach, Fla., hospital settling for $85 million (RMC 3/10/14, p. 1), says Wade, who is not involved in the Citizens case but is the “compliance expert” to Halifax Health’s board, a position mandated in its corporate integrity agreement. The ER doctors at Citizens Medical Center allegedly collected 50% of the revenue stemming from their patient referrals to the Chest Pain Center, while in Halifax, “the amount of money that went into the bonus pool arguably varied on the volume or value of referrals, but was divided based on work relative value units, so it was tied to personally performed services,” says Wade. In the Halifax case, a federal judge ruled that a bonus pool for six medical oncologists violated the Stark law, but declined to opine on compensation for three neurosurgeons, and the case settled before trial (RMC 11/18/13, p. 3).

**Fair-Market Value Was Another Focus**

The other allegation in the Citizens Medical Center case that’s part of the settlement centered on fair-market value. The hospital entered into employment agreements with five cardiologists starting in 2007 and 2008, and paid them considerably more than they earned in private practice, the complaint alleged. Under the employment agreements, the hospital billed for all medical services provided by the cardiologists in their offices and the hospital, did collections, paid them a salary, gave them health and dental insurance, provided limited malpractice insurance, paid for continuing medical education and furnished dictation services, the complaint said. The hospital agreed to pay “above-market salaries and fringe benefits in exchange for Medicare and Medicaid patient referrals from the cardiologists,” the complaint alleged.

Wade says apparently there was no fair-market valuation of the compensation at the time. “You always have to focus on what you’re paying,” he says. To comply with Stark, financial arrangements have to be commercially reasonable as well (RMC 3/16/15, p. 1) and meet other requirements, such as memorializing the agreement in writing and setting compensation in advance.
Citizens Medical Center didn’t admit liability in the settlement. Its attorney, Gary Eiland, who is with King & Spalding in Houston, said as soon as the lawsuit was unsealed, “the hospital implemented appropriate corrective actions. This is not continuing conduct.” Once the hospital was aware “these arrangements could be viewed as suspect, they changed them,” Eiland says. For example, the hospital got fair-market appraisals of its cardiology compensation. He says the hospital already had a compliance program, but it’s more robust now. The settlement does not include a corporate integrity agreement.

The whistleblowers will get $5.98 million of the settlement amount, which is 27.5%, at the high end of what whistleblowers can recover under the False Claims Act, apparently because the government intervened only to effectuate and finalize the settlement. Other allegations in the complaint were dismissed by the whistleblowers with prejudice.

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**Government Will Show Hand in FCA Negotiations if It Trusts the Defense**

The financial hit the government takes is not always the deciding factor in whether to pursue a False Claims Act case, according to a federal prosecutor.

The amount of damages matters, but “my experience is, if the conduct is serious” — for example, the physician’s judgment was “corrupted” and risked patient harm — “we will pursue recovery even if the damages are not that large,” Charles Graybow, civil health care fraud coordinator for the U.S. Attorney’s Office for the District of New Jersey, said at a recent Health Care Compliance Association webinar.

Graybow described other factors the government considers when approaching false claims cases and entering into settlement negotiations.

For one thing, by the time the U.S. attorney’s office in New Jersey meets with defense counsel to discuss a case, a lot has happened behind the scenes. For example, prosecutors have talked to witnesses, researched legal documents and met with relevant experts (e.g., FDA) to explore whether patients were harmed, Graybow said. “There are negotiations within negotiations before even talking about settling a case,” he said. When they finally sit down with defense counsel, prosecutors run the tentative allegations up the flagpole. “A really important point is sitting with defense counsel and giving them the government’s perspective and testing our theories against what the defense has to say,” he said. The defense’s response may prompt prosecutors to investigate their case further — maybe interview more witnesses and review more documents. “We welcome when defense counsel can have robust discussions with us and test out our theories and that could spark more investigation,” Graybow said. “They may be surprised the government will need to do more due diligence, while defense counsel has told clients the government is done.”

Cooperation is another factor the government takes into account during the false claims investigation and settlement process, but there’s more to it than meets the eye. “Cooperation can potentially influence the multiplier on the civil side, but the civil side typically requires the defendant to pay some multiplier,” he said. And just answering a subpoena promptly is “welcome, but not the kind of cooperation we are requiring. It’s good for establishing rapport, but true cooperation is some kind of disclosure that advances the investigation.” One example is waiving attorney-client privilege. However, rapport is important to negotiating a settlement.

The relationship between the two sides is also important in terms of sharing information, Graybow said. The government is willing to show more of its cards if it trusts the defense, he said. “The better rapport, the more comfortable folks on my side of the table are about sharing information” — such as disclosing the identity of witnesses or consultants hired by the government; revealing the existence of a whistleblower (earlier than required); producing a redacted copy of the complaint; and maybe identifying the whistleblower sooner.

**Criminal Case Is ‘Elephant in the Room’**

Before he tackles false claims allegations, defense attorney Jack Wenik said at the webinar that he checks whether the government is pursuing a criminal case against the provider. “The elephant in the room is a criminal case,” especially since the Department of Justice in September said all False Claims Act lawsuits filed by whistleblowers will be immediately reviewed by prosecutors in the criminal division, in addition to the usual review by lawyers in the civil division (RMC 9/22/14, p. 1).

“With the new [enforcement] tools the government has, the line between criminal and civil has been blurred,” said Wenik, who is with Epstein, Becker & Green in Newark, N.J.

Once criminal allegations are “off the table,” the defense has to look closely at the civil allegations before entering settlement negotiations, he said. For example, if the case questions medical necessity, “the retention of medical necessity experts is crucial.” If it’s a Stark or kickback case, with allegations that payments were a cover for kickbacks, you need valuation experts. “You want all of that available before you enter into negotiations,” according to Wenik.

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But keep in mind the potential costs of litigating when considering the settlement. “One of the bigger factors nowadays is the litigation costs of defending the case,” he said. The government’s e-discovery requests — including emails and spreadsheets — and the costs of experts add up fast.

During initial meetings with prosecutors, Wenik tries to get them to see the case — evidence and witnesses — through the defense’s eyes. “The government has a head start. Because of that, they may be hearing only from the perspective of the whistleblower,” he said. “It’s very important to the defense side, before talking about the nuts and bolts of the settlement, to get the government to see the other perspective….I may bring in my witnesses so [the assistant U.S. attorney] can hear what they will say.”

Also early in the process, Wenik lets the government know about the defendant’s corporate citizenship. “I like to come in and say ‘here are the reforms we have already made to our policies,’” he said. “It’s important to do that early on and…show good faith. We are not just advocates. We are part of the process.”

A potential settlement also plays a role in a defendant’s pending merger, acquisition or joint venture, Wenik said. “Is that transaction thwarted because you have to disclose in due diligence the existence of the false claims action?” That factor may make you want to settle sooner or later. There’s also the risk that “exposing to the government that the transaction is out there [will increase the price],” he said.

In terms of damages, Graybow said the government may consider the defendant’s ability to pay a settlement amount, but only if the defendant raises the issue. “Anything with ability to pay is a voluntary process,” he said. And it’s not an easy hill to climb; defendants have to produce detailed financial documents and answer the government’s questions. However, the government is a little more open to giving them extra time to pay settlement amounts.

Settlements are negotiated by the regional U.S. attorney’s office, but a trial attorney from the main Department of Justice also will be involved. “DOJ has to sign off on most settlements,” Graybow said. If providers want alleged Medicaid false claims resolved at the same time as Medicare or other federal false claims are resolved, they should speak up. “I have to bring in the state,” he said. “Otherwise, I am negotiating a Medicare number.” Similarly, he is negotiating a civil case unless the defendant requests a global resolution letter. The criminal and civil divisions of the U.S. attorney’s office can negotiate with the defendant together and wrap it all up in one fell swoop.

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New CMS Transmittal Clarifies Issues for Critical Access Hospitals

State surveyors will exclude observation beds when determining whether critical access hospitals fall within the 25-bed maximum allowed by the Medicare conditions of participation, according to Transmittal 138, which revised the state operations manual. That’s one of a host of revisions to the interpretive guidelines in the state operations manual rolled out by CMS on April 7. The manual is used by state surveyors to determine, on CMS’s behalf, whether critical access hospitals comply with Medicare conditions of participation.

The nation’s 1,300 critical access hospitals (CAHs), which are paid 101% of reasonable costs for inpatient and outpatient services instead of MS-DRGs and APCs, are restricted to 25 beds. But there has been some confusion around whether that included observation beds, says Brock Slabach, senior vice president of the National Rural Health Association in Leawood, Kan. “What CMS has done has been helpful to many providers in defining observation beds as being additional to those 25 beds,” he says. “A number of state survey agencies wanted to count 25 as the total number of beds, including observation beds. Some states have stricter application of that rule than others. This provides direction so everyone is treated equally.” He notes that CMS defines “observation beds” as any kind of outpatient bed (e.g., sleep studies and emergency services).

When Is a Bed Not a Bed?

CMS wants surveyors to pay close attention to this line it drew in the sand. “Beds used solely for patients receiving observation services are not included in the 25-bed maximum, nor in the calculation of the average annual acute care patient length of stay. This makes it essential for surveyors to determine that CAHs with observation beds are using them appropriately, and not as a means to circumvent the CAH size and length-of-stay limits,” the operations manual says.

In fact, a theme of the revisions, which appear in the section on provider certification of the CMS State Manual System (Pub. 100-07), is bringing uniformity to surveys of compliance with the conditions of participation, Slabach says. Surveyors from different states often enforce provisions differently so there hasn’t always been consistency in CAH operations, Slabach says.

Here are some other key revisions to the interpretive guidelines:

• C-0260: CMS has gotten much more specific about reviews of medical records by doctors of medicine and osteopathy at critical access hospitals. Before, the interpretive guidelines stated that physicians had to “periodically review and sign” the records of patients treated by nurse practitioners, clinical nurse specialists or physician assistants at the CAHs. Now CMS distinguishes between inpatient and outpatient records, and says physicians must review and sign the records of all inpatients treated by the nonphysician practitioners and “periodically” review and sign a sample of outpatient records but “only...
to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician.” Slabach says this gives critical access hospitals a better idea of CMS’s expectations. The agency has recommended a sample size of 25% of outpa-
tient records, he says.

♦ C-0271: CMS fleshes out its definition of “medical direction” and “physician supervision.” The manual has a long explanation of what CMS considers physician availability and supervision. Complying with these requirements is not an issue for larger CAHs, which always have physicians available. “But frontier facilities may only have one or two doctors on staff,” Slabach says. CMS gives CAHs some flexibility, and acknowledges the role that technology, such as telemedicine, can play in providing medical direction and oversight. “For CAHs that offer a range of more complex services, have more than one MD/DO on staff, and have busy emergency departments and/or extensive outpatient services, an on-
site visit by an MD/DO only once every week or every two weeks, for example, would be grossly inadequate,” the manual states. “On the other hand, a bi-weekly on-
site visit could be unduly burdensome as well as unnec-
essary for a small CAH in a remote rural area that offers very limited services and has a low patient volume.”

In a strange change, CMS says in the manual that observation in CAHs ends when the physician orders the patient discharged, transferred or admitted. That’s in-
consistent with the Medicare claims processing manual, which states that observation ends when services are concluded, says Ronald Hirsch, M.D., vice president of regulations and education for Accretive Physician Advisory Services. “It may only be a couple of hours, but CAHs are paid on cost, so every hour of care costs money and they deserve reimbursement for it,” he says. And which policy should CAHs follow? It’s unclear and leaves CAHs on the horns of a dilemma, he says.

Contact Slabach at bslabach@nrharural.org and Hirsch at rhirsch@accretivehealth.com. View the revi-
sions to the manual at http://tinyurl.com/p8pzmzq.

**OIG Pushes Board Involvement**

*continued from p. 1*

a turning point, with the compliance tone at the top now definitively starting with the board of directors “to en-
sure the C-suite executives view compliance neither as an irritant nor as something to pay lip service to, but as an every day, every transaction, every event commitment,” Trusiak says.

The guidance expects boards to be “active,” says for-
mer OIG senior counsel Brian Bewley, who is with Polsi-
nelli. “It places responsibility on board members to know what’s going on in the industry as a whole and with the particular risks in their organizations.”

There’s a secondary gain for enforcement, Trusiak says. The guidance gives the Department of Justice another data point to use during the most confounding part of the false claims settlement process: deciding appropriate damages — single, double, treble, with or without per-claim penalties. During settlement discus-
sions around financial penalties, prosecutors may take into consideration whether boards play an affirmative role in compliance, which has now been defined in the guidance, he says. They can search board minutes to see the prevalence of words like “HIPAA” and “Stark” as a means to assess the board’s commitment to compliance. “You need objective markers to inform your judgment,” he says. Is the organization committed to “growth or compliant growth?”

**OIG: CCOs Should Not Report to Counsel**

The guidance gives board members practical advice for compliance oversight, which should evolve in re-
sponse to new risks, new reimbursement methods and industry consolidation. To benchmark their organiza-
tions, boards should rely on familiar resources, including Federal Sentencing Guidelines, OIG compliance-program guidance and corporate integrity agreements. It’s fine to scale them to smaller organizations, which may use “available personnel, rather than employing separate staff, to carry out the compliance and ethics program,” as long as they show the same commitment to compliance and ethical conduct as larger organizations, the guidance states. Boards may have to be more hands-on with com-
pliance at smaller organizations.

It should be crystal clear to board members how various departments — including compliance, legal, audit, human resources and quality assurance — relate to each other. OIG makes a point of saying compliance officers should not be under anyone’s thumb because it compromises their effectiveness. “OIG believes an organ-
ization’s Compliance Officer should neither be counsel for the provider, nor be subordinate in function or posi-
tion to counsel or the legal department, in any manner,” the guidance states. “While independent, an organiza-
tion’s counsel and compliance officer should collaborate to further the interests of the organization. OIG’s position on separate compliance and legal functions reflects the independent roles and professional obligations of each function; the same is true for internal audit.” Some com-
pliance officers have struggled with interference from internal counsel (RMC 2/23/15, p. 1), which may under-
mine transparency.

Boards may also want to have one member who is a regulatory, compliance or legal professional, or at least consult one periodically, the guidance says. “The
presence of a professional with health care compliance expertise on the Board sends a strong message about the organization’s commitment to compliance, provides a valuable resource to other Board members, and helps the Board better fulfill its oversight obligations.”

More frequent executive sessions with compliance officers and other managers also is worth considering, the guidance says. It will promote dialogue and defuse tension with senior leaders — who aren’t invited — because they get suspicious when a rare executive session is scheduled. Trusiak says this bodes well for compliance because boards may take a longer view of the best interests of the hospital than senior executives do. For example, a merger, physician practice acquisition or joint venture could increase volume in the short run, but hospitals also have to consider Stark, kickback and anti-trust implications with the help of lawyers well-versed in these risks.

Boards Should Identify Risk Areas

Identifying risk areas is another obligation of the board, which should ensure management “consistently reviews and audits risk areas, as well as develops, implements, and monitors corrective action plans,” the guidance states. Boards also have to “set and enforce expectations” for getting compliance information from management. “It may be helpful and productive for the Board to establish clear expectations for members of the management team and to hold them accountable for performing and informing the Board in accordance with those expectations,” the guidance notes. Management may be required to report on internal and external investigations, significant audit findings, hotline calls, “all allegations of material fraud or senior management misconduct, and all management exceptions to the organization’s code of conduct and/or expense reimbursement policy.”

There are a lot of incentives for board members to foster compliance programs that identify compliance failures and voluntarily report them to the government, the guidance notes. For example, organizations are compelled by the 60-day rule, which requires providers to return Medicare and Medicaid overpayments within 60 days of identifying them. “A Board would be well served by asking management about its efforts to develop policies for identifying and returning overpayments.”

The emphasis on board and management responsibility for compliance is remarkable, Trusiak says. “They’re redefining ‘governance.’ They want board members to become involved in management to the extent it implicates compliance matters,” he says. The guidance, for example, encourages boards to ask how performance evaluations advance the organization’s commitment to compliance and whether bonuses or “claw-backs” should be used to influence compliant behavior. “These are generally management areas,” says Trusiak, former compliance officer for Kaleida Health. “They’re not concerned with labels.”

Now that the guidance is out there, Bewley says board members should benchmark their performance and make changes if necessary. The guidance is compelling because it is the consensus of both the government and the industry groups, he notes.

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NEWS BRIEFS (continued)

guilty to one count of mail fraud stemming from phony vendor invoices that defrauded his employer of nearly $10 million over a 14-year period, the U.S. attorney said (RMC 3/30/15, p. 1). Wild, who will be sentenced on June 29, faces up to 20 years in prison. Visit http://tinyurl.com/nxkrhad.

♦ The Department of Justice said on April 21 it has intervened in three false claims lawsuits against HCR ManorCare, which operates 281 skilled nursing facilities (SNFs) in 30 states. According to DOJ, which filed a consolidated complaint, the SNF chain submitted false claims to Medicare and TRICARE for rehabilitation services that weren’t medically necessary. ManorCare, which is owned by The Carlyle Group, allegedly pressured SNF administrators and therapists to meet “unrealistic financial goals” that led to the provision of medically unreasonable and unnecessary services, the Department of Justice alleges in its complaint. “ManorCare allegedly set prospective billing goals designed to significantly increase revenues without regard to patients’ actual clinical needs and threatened to terminate SNF managers and therapists if they did not administer the additional treatments necessary to qualify for the highest Medicare payments,” DOJ alleges. “ManorCare also allegedly increased its Medicare payments by keeping patients in its facilities even though they were medically ready to be discharged.” This is not the first SNF company to be accused of false claims partly or wholly related to therapy or to settle allegations along these lines. Extendicare Health Services Inc. in October 2014 agreed to pay $38 million. The Department of Justice alleged that Extendicare provided “materially substandard nursing services” at 33 of its skilled nursing facilities in eight states from 2007 to 2013 and that the SNF company and its subsidiary, Progressive Step Corporation, allegedly billed for medically unnecessary rehabilitation (RMC 10/20/14, p. 5). In September 2014, Episcopal Ministries to the Aging Inc., a Maryland SNF company, agreed to pay $1.3 million to settle allegations that it submitted false Medicare claims for unreasonable or unnecessary rehab provided by its contractor, RehabCare Group East Inc., a subsidiary of Kindred Healthcare Inc. (RMC 9/22/14, p. 1). There are other cases as well. Read the Justice Department press release and complaint about ManorCare at http://tinyurl.com/15bzdkm.

♦ A Louisiana physician pleaded guilty to health fraud on April 23 in connection with false home health certifications, the Department of Justice and U.S. Attorney’s Office for the Eastern District of Louisiana said. Winston Murray, M.D., 62, of Hammond, pleaded guilty to one count of conspiracy to commit health care fraud and two counts of health care fraud. He is the ninth person to plead guilty in the alleged home health fraud scheme; the other four people accused in the case are set to go on trial next month. Murray, who ran a clinic, wrote home health care referrals for Medicare beneficiaries who knew they were not homebound, the Justice Department said. The referrals allegedly were used by Interlink Health Care Services Inc., Lakeland Health Care Services Inc. and other home health companies to allegedly bill Medicare for services that were not medically necessary or not provided. Medicare paid the home health companies about $50.7 million on these claims. Visit http://tinyurl.com/pk945cb for more information.

♦ Family Dermatology, P.C., agreed to pay $3.24 million to settle false claims allegations around improper financial relationships with some of its physicians, the Department of Justice and the U.S. Attorney’s Office for the Northern District of Georgia said on April 21. Family Dermatology owns a dermatopathology lab in Georgia and dermatology practices in the eastern United States. Its settlement with the Justice Department resolves allegations that some financial arrangements with physicians violated the Stark law. “Family Dermatology employs a number of dermatologists as independent contractors and it has routinely required them to use Family Dermatology’s in-house pathology lab, which operated under the name Nelson Dermatopathology, for their pathology services. The government alleged that Family Dermatology’s financial relationships with a number of these physicians did not comply with the requirements of the Stark Statute, and that Family Dermatology improperly billed Medicare for dermatopathology analyses performed by Nelson Dermatopathology on specimens that were sent to the laboratory by these employed physicians,” the Justice Department alleged. The case was initially filed by three separate whistleblowers, two of whom are physicians. For more information, visit http://www.justice.gov/usao/gan.
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