could find yourself with violations that could easily have been prevented," he says.

New management or owners also can learn from this case, Thornton adds.

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Hospitals Face Many Hurdles With Growing Role of Quality

Opposing forces are facing off in the quality arena, posing a great challenge for hospitals. In one corner is the "new paradigm," which represents the shift to a payment system linked to quality, enforcement based on unnecessary or substandard care and hospital performance in the glare of public reporting of quality measures. In the other corner are longstanding practices, such as independent medical staffs and traditional peer review, that make it harder to accomplish the changes necessary to thrive under the new paradigm, lawyers say. Hospitals should consider taking certain steps to adjust to the dominant role quality is playing in all arenas, including breaking down walls between compliance and quality and forging closer ties with physicians, lawyers say.

"There are structural and process changes that must occur for hospitals to function in the new paradigm," says Chicago attorney Janice Anderson, who is with Foley & Lardner LLP. She has asked OIG for an advisory opinion on the fraud-and-abuse implications of a model for hospital-physician collaboration that will help further the new paradigm. Hopefully, OIG will release the opinion soon.

CMS (and other payers) are using payment to leverage higher quality care. This is happening in three ways, according to Anderson and Nathaniel Lacktman, an attorney in Foley & Lardner's Tampa, Fla., office:

(1) CMS pays hospitals the full marketbasket update only if they report specific quality data (e.g., the percentage of the time the hospital immediately administered beta blockers to patients presenting with acute myocardial infarction).

(2) CMS plans to implement, by Oct. 1, its value-based purchasing plan (though congressional approval is still needed). Under this pay-for-performance plan, hospitals would be docked 5% of their DRG payments up front and have to earn it back by proving they provide quality care. Similarly, a year ago, CMS started the Physician Quality Reporting Initiative (PQRI). If physicians report on any of 119 quality targets applicable to their practices, they receive a bonus worth 1.5% of their Medicare-allowed charges. "Medicare has proposed a cut of over 10% to the physician fee schedule for 2008, redirecting payments to PQRI. Congress delayed implementation to July 1, 2008," Anderson says.

(3) CMS has halted payments for eight hospital-acquired conditions on the grounds that they reflect poor quality, effective Oct. 1, she says. The conditions are object left in during surgery, air embolism, blood incompatibility, catheter-associated urinary tract infection, pressure ulcers, vascular catheter associated infection, surgical site infection following coronary artery bypass graft and falls. And hospitals must assign one of five present-on-admission indicators to all principal and secondary diagnosis codes.

The government also seeks to drive quality of care by making it transparent through public reporting, Anderson and Lacktman say. The data gathered by the government are put into the public domain so that consumers can steer clear of hospitals with unimpressive quality data and/or that show no signs of improvement (e.g., for five years in a row, Hospital ABC has given aspirin to only 60% of patients treated for heart attack when they are discharged, which means it has not improved on this key quality indicator). "To the extent some of this data was publicly available five years ago," it was not user friendly, Lacktman says. "But with Hospital Compare and Nursing Home Compare, the government is taking this data, crunching it and presenting it in a way that consumers can easily understand so they can find the best hospital in their community," he says.

Public reporting in February got a boost from HHS, which proposed rules to create a system of voluntary patient-safety reporting through patient safety organizations. The rule fleshes out the Patient Safety and Quality Improvement Act. But final rules are probably not going to be published anytime soon.

With all the data flying around, however, compliance must be top of mind. "Hospital data must be managed to ensure appropriate data is being reported" and that it's accurate, Lacktman says. As with any data, reporting false information to the government can get a hospital in a world of trouble. This is one reason why the "quality department must be shown how to communicate with the compliance department," he says.

"It's important for hospitals to have an auditable trail to support the data they submitted because it will be scrutinized," Anderson adds.

Enforcers Punish Worthless Services

The enforcement picture has changed to encompass quality-related allegations, Anderson says. The Department of Justice is using the False Claims Act to attack failures of care, not just straight financial crimes against Medicare. Traditional theories to recover false claims, such as unbundling, duplicate payments and billing for

services not rendered, have expanded to include quality-of-care theories.

For instance, the feds may accuse a hospital of billing Medicare for medically unnecessary or worthless services or for care that fails to meet conditions for payment, Anderson says. Or they may allege a False Claims Act violation under the express or implied false certification theories, Anderson says. "The certification theories are based on the idea that every claim you sign is a certification that it was medically necessary and meets the requirement for payment. If it's not medically necessary, the government has an argument that you

Probing Questions for Evaluating Compliance Programs

These "non-generic" questions are designed to help compliance officers (and other executives) think hard about the systems that exist — or are lacking — to prevent and detect compliance problems in their organizations, says Tony Capullo, president of Professional Provider Services, a consulting firm in Fort Lauderdale, Fla. Contact him at TCapullo@aol.com.

(1) If the compliance officer left the company, would the next compliance officer be able to come in and pick up where he/she left off? What would be the learning curve? What would be the implication of the learning curve?

(2) What is your ultimate objective with regard to the compliance system for your company?

(3) What would you change about the current way that the company reviews physician contracts?

(4) How do you determine that a contract has met the smell test for the anti-kickback and Stark statutes?

(5) What specifically do you look at when reviewing physician contracts?

(6) If there was a glitch in the organization's internal control system, how would you discover it? How long would it take you to find it? Who would discover it?

(7) Describe your system for measuring the effectiveness of the hotline.

(8) How does the organization address government focus areas, such as audit plans from OIG?

(9) What system is in place to ensure that the training addresses current issues, such as new regulations or hot topics in the industry?

(10) How often is a compliance billing audit conducted, and what documents (e.g., OIG Work Plan, fraud alerts, advisory opinions and OIG audit reports) are used to assist in developing the audit program?

(11) How does the organization ensure that independent contractors are made aware of, and adhere to, the organization's compliance program?

(12) Does the organization have a written investigation protocol governing the conduct of internal investigations?

(13) What has been the company's experience with testing the effectiveness of the internal control system?

(14) Describe your system to ensure that billing systems function properly and result in correct payment.

(15) Hospital-specific question: What controls do you have in place to ensure that the organization updates and maintains the chargemaster?

(16) What is the price the organization may pay for not addressing compliance issues? (Does the person know the range of consequences, including loss of profit, overpayment returns and potential False Claims Act lawsuits?)

(17) How has not having a consistent system for auditing the billing impacted your profit?

(18) For the CEO: Describe how audit report recommendations are followed up on to determine their effect on operations and money. How has your compliance program affected your profit? For example, an outdated chargemaster is costing the hospital a lot of money as well as endangering its compliance.

(19) Does the organization review the compliance plan and update it at least annually to see whether it follows the latest OIG compliance guidance and other official commentary? In other words, is the organization "audible ready," a football term meaning it's ready to adapt the system quickly to changed circumstances?

(20) When you hear "effective internal controls" — checks and balances — what comes to mind? Capullo says internal controls and compliance overlap. Internal controls are designed to prevent, detect and correct glitches in an organization's business processes. For example, Capullo once audited a lab company and found a lack of a key internal control caused a big compliance problem. The salespeople inappropriately had access to the accounts receivable (AR) computer files, and they were manually writing off copayments. "That was a huge risk," he says. "It should never have happened." The corrective action? Password protection for AR.

falsely certified your claim," she says. An expressly false claim is a claim that falsely certifies compliance with a particular statute, regulation, or contractual term, where compliance is a prerequisite to payment. An implied false certification claim is based on "the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment," Lacktman says. Judges have not been as supportive of implied certification, Anderson notes.

For example, in November 2006, Larkin Community Hospital in South Miami and its current and former owners participated in a $15.4 million settlement of a false claims lawsuit alleging the hospital paid kickbacks to physicians for patient referrals that led to medically unnecessary treatments on elderly patients.

Even with the emphasis on quality forcing a lot of rethinking in hospitals, change won't come easy. Here are five problems hospitals face in making the new paradigm work, Anderson and Lacktman say:

(1) Hospital peer review and quality management are not structured to drive quality of care necessary for the new paradigm. Peer review focuses on "bad apples," not quality improvement, Anderson says. Physicians judge their friends and competitors, who may be unwilling to discipline their colleagues, she says. "Anyone in the industry would admit these processes won't be successful in making changes under the new paradigm," she asserts. Peer-review delays can lead to more poor quality and unnecessary care. For example, the United Memorial Hospital case in Michigan "was failed peer review," Anderson says. (A physician was convicted for providing medically unnecessary pain management procedures, which came to the government's attention after a patient died. The hospital also entered into a deferred prosecution agreement, but prosecution was not consummated when the hospital implemented reforms and paid a fine.) A Dec. 4, 2007, article in the *Annals of Internal Medicine* reported that almost half of physicians don't report their peers' medical incompetence.

(2) Medical staff structure is too loosely organized for the new paradigm, which requires enforcing a new quality-improvement policy or procedure. There's no mechanism to require members, for example, to always give patients an ACE inhibitor for left ventricular dysfunction, she says. Many hospitals have become a combination of a "cadre of medical-staff physicians who barely step foot in the hospital and a cadre of hospital-focused physicians" — hospitalists, laborists, surgicalists — so hospitals are grappling with what they are required to do to improve care when their relationships with some physicians are so tenuous, Anderson says. Complicating matters is a blurring of specialty lines. For example, radiologists, cardiologists and neurologists are competing to perform interventional procedures. This challenges the traditional departmental structure of the medical staff as it is called on to credential and privilege physicians for procedures that cross departmental lines. "It's the responsibility of the medical staff to oversee quality, but they lack a structure in place [to do this]," she says. Now,

Steps Hospitals Can Take to Increase Focus on Quality

Hospitals are facing legal and structural hurdles in coping with the increasing role of quality in payment and enforcement (see story, p. 1). Chicago attorney Janice Anderson, who is with Foley & Lardner LLP, and Nathaniel Lacktman, an attorney in the firm's Tampa, Fla., office, say that in addition to performing a quality audit, hospitals should think about taking some steps to adapt to quality's growing role:

◆ ***Integrate quality and compliance.*** Make sure employees in the peer review, quality assurance and utilization review departments understand and are educated about the compliance risks associated with their work.

◆ ***Establish procedures so quality problems like unnecessary surgeries are referred to the compliance department.*** But "you have to be careful about how you do this" to avoid violating state laws on peer-review confidentiality, Anderson says. "As you set up a structure to integrate quality and compliance, be careful you don't inadvertently waive privilege."

◆ ***Improve board education and oversight.*** "The board needs to frame an agenda for quality," Anderson says. "Work with administration and staff to come up with an agenda for quality for the organization." Consider recruiting a board member with expertise in quality, she adds.

◆ ***Devise structures for hospital-physician collaboration to promote quality.*** Anderson hopes she has devised a model that strikes the right balance and that OIG will approve in a forthcoming advisory opinion. That opinion should shed light on what OIG considers permissible in this arena.

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she adds, the Joint Commission is mandating how peer review should be done, using evidence-based medicine.

(3) Too much siloing of responsibility between departments. In particular, compliance doesn't seem to talk to quality assurance or peer review much, Lacktman says. Lew Morris, chief counsel to the HHS Inspector general, "has keenly stressed this as an organizational problem," Lacktman says. "What this means is, if [the quality department] discovers an issue, how do they make sure the compliance implications of that quality issue are addressed?" For example, suppose only the nurses know that a top surgeon performs medically unnecessary surgeries. Referring that physician to peer review may not be enough because that process is notoriously long, and meanwhile, the potential false claims are piling up, Lacktman says. It's critical for the compliance officer to be informed of this. And "before they can even know when or what to report, the quality people must be given at least a general understanding of the compliance implications of poor quality of care," Lacktman says.

(4) Lack of board education and oversight over quality. Boards historically have been focused on hospital finances, not quality. An April 2006 article in the *Joint Commission Journal on Quality and Patient Safety* found "the level of knowledge of landmark [Institute of Medicine] quality reports among CEOs and board charts was remarkably low." OIG in recent guidances — put out jointly with the American Health Lawyers Assn. and the Health Care Compliance Assn., respectively — has been encouraging boards to commit to a quality agenda, she says. "They remind boards their fiduciary obligations include overseeing and driving quality of care, she notes.

(5) Lack of effective physician-hospital collaboration strategies. Hospitals need physicians' help to accomplish quality targets and earn pay-for-performance incentive payments, but coaxing and scolding alone don't usually change physician behavior, Anderson says. However, the fraud-and-abuse laws and regulations "make it hard to align with physicians financially around quality," she says.

Perform a Quality Audit

Notwithstanding the intensity of the problems facing hospitals as they seek to improve quality, there are solutions, the lawyers say. For starters, they recommend a quality audit (for more solutions, see box, p. 5). "Hospitals have been auditing billing systems and physician financial arrangements, but there is as big a compliance risk with quality," Lacktman says.

A quality audit is a unique, specialized review, somewhat similar to an independent compliance risk assessment in the way it is performed. But the focus is on those issues affecting quality of care and the legal risks they pose. For example, a quality audit has greater focus on compliance with the Medicare conditions of participation instead of the traditional billing rules, Lacktman says. And the audit would look at processes around quality reporting. Does the hospital track quality reporting on indicators? Does it have a quality improvement plan surrounding an issue if the results are not that good? It would examine quality-of-care issues in utilization review, board involvement and oversight, cross-department communication, medical staff, and relevant state laws related to quality. A quality and legal risks audit is the first step a hospital should take to understand and address quality-of-care issues, Anderson and Lacktman say.

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Infusion Billing Baffles, Again

continued from p. 1

"From a coding perspective, injection and infusion is the hottest topic out there," says Janice McDonnell, compliance specialist with the University of Connecticut Health Center. It's also big with the government. On March 7, the U.S. Attorney's Office for the District of Connecticut announced that Yale-New Haven Hospital will pay $3.8 million to settle allegations that it improperly billed for chemotherapy, infusion and blood transfusions between 2000 and 2005. In 2006, multiple hospitals settled allegations of infusion and transfusion billing errors with U.S. attorneys' offices in Pennsylvania. The total settlement amount reached $8 million.

"Hospitals have difficulty with infusion coding simply because it's been so dynamic over the past few years," says Delena Howard, a senior associate in the Jacksonville, Fla., offices of consulting firm KPMG. "I have found that determining what the initial service is can be very difficult." However, she says, the American Medical Assn. (AMA) recently published a "hierarchy" that sheds light on a decision that sounds like it would be simple — the initial service came first, right? — but isn't.

"Billing of infusion has been a difficult transition" over the past two to three years, says Bob Masters, vice president of the consulting division of Medical Bureau/ROI.

The big compliance headache has been the shift from billing for infusion by session to billing for infusion by time.

Until recently, CMS has directed hospitals to bill Medicare per session of infusion because Medicare wanted to pay for the session rather than its components, Plas-