HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

COMPLIANCE TODAY

Volume Twelve
Number Five
May 2010
Published Monthly

Meet

Miaja Cassidy Director of Healthcare Compliance at Target

PAGE 14

Earn CEU Credit

WWW.HCCA-INFO.ORG/QUIZ — SEE PAGE 41

Feature Focus:

Managing security risks in business associate relationships

PAGE 32

COMPLIANCE 101: INTEGRATING THE HOSPITAL COMPLIANCE PROGRAM WITH THE MEDICAL STAFF BYLAWS

PAGE 23

This article, published in Compliance Today, appears here with permission from the Health Care Compliance Association. Call HCCA at 888/580-8373 with all reprint requests.

Integrating the hospital compliance program with the medical staff bylaws

By Howard E. O'Leary, Jr.

Editor's note: Howard E. O'Leary, Jr., is Of Counsel with the Dykema law firm. He is a former Assistant United States Attorney and former Chief Counsel and Staff Director of the U.S. Senate Antitrust and Monopoly Subcommittee. Mr. O'Leary may be contacted by telephone in Washington, DC at 202/906-8601 or by e-mail at holeary@dykema.com.

You are a relatively new compliance officer at Ozymandias Memorial Hospital, responsible for administering its fraud and abuse compliance program, which includes following up on complaints on the compliance program hotline. After a few somnolent months on the job, you are awakened by an alarming voicemail from an anonymous hotline caller who asserts that Oz (a hospital nickname) has been submitting false claims to Medicare and other federal health care programs for a number of years. The claims are for medically unnecessary elective angiogram, elective angioplasty, and elective stenting procedures. According to the caller, these procedures were performed by Dr. T. Bill Greedly. You are familiar with Dr. Greedly, who is the head of an area cardiology group that accounts for a large number of Oz's cardiology procedures. Oz gets the lion's share of the Greedly Group's referrals, but its physicians also have staff privileges at a neighboring hospital that is Oz's principal competitor.

The anonymous caller's allegations are that Dr. Greedly falsely diagnosed the existence of coronary artery disease, falsely identified coronary blockages, recorded false diagnoses in patients' charts, and put patients at risk by performing these medically unnecessary procedures. The anonymous caller's voicemail names four patients as examples of instances where Dr. Greedly caused Oz to submit false claims to Medicare.

The caller also provides names of a number of Oz nurses and medical technicians who allegedly have complained to their superiors after witnessing unnecessary angioplasty procedures by Dr. Greedly. You happen to know quite well one of the nurses named and decide to talk to her. She unloads on Dr. Greedly and states that her complaints and other complaints to the Head of Cardiology and your predecessor were simply ignored.

You wrestle with the following questions:

- Are the anonymous caller's allegations true or is this a "gray" area where medical opinions about the necessity of the services provided will differ?
- If the allegations are true, is Dr. Greedly's conduct endangering the health of Oz patients?
- If true, how many nurses and technicians complained about Greedly, to whom, and why wasn't anything done about it?
- Are there records and e-mails of these complaints and where are they?
- Did Ozymandias Memorial submit its related facility fee claims "willfully" in violation of myriad federal criminal statutes ("knowingly" within the meaning of the civil False Claims Act) as the result of mere negligence; or did it rely reasonably on Dr. Greedly's medical judgment—correct or not—that the services provided were "medically necessary"?
- Is this an "overpayment" matter that can be resolved quietly by simply repaying Medicare and others for the claims submitted incorrectly?
- Or will there be enough fraud indicia so that the safer course is to participate in the US Department of Health and Human Services (DHHS) Office of Inspector General (OIG) voluntary disclosure program?
- If the latter, will Oz be saddled with an OIG-imposed corporate integrity agreement (CIA) and attendant bad publicity?
- What sort of disgruntled patient malpractice exposure might such publicity cause?
- Could Dr. Greedly and Oz already be the subject of a *qui tam* complaint filed under seal, and is the anonymous caller the plaintiff (or "relator") in such an action?
- Is the anonymous caller also a current employee, someone who will be reporting back to OIG on how you and others respond to his allegations?

These questions and their possible ramifications are enough to give you a headache. Because you are not a lawyer, you head for the office of Oz's general counsel (GC), someone whose pay grade is higher than your own.

Cloaking the investigation under the attorney-client privilege

The GC's reaction is that the CEO must be informed immediately. After being briefed, the CEO tells you and the GC that he has heard negative hospital "scuttlebutt" about Dr. Greedly and his methods of practice, but nothing concrete. The CEO and GC consider briefing the chief of the medical staff about the Greedly allegations, but defer any such discussion until after some additional investigation has been done. The GC recommends hiring Snooper & Grill, a local law firm, to team up with you to conduct an internal investigation, in hopes that the results will fall within the

Continued on page 24

 ...continued from page 23

attorney-client privilege. The CEO agrees, but asks that you and Snooper & Grill proceed cautiously. "If at the end of the day," the CEO says, "these are questions of medical judgment on which reasonable physicians can disagree, we want to be careful not to damage Dr. Greedly's reputation or the hospital's relationship with the Greedly Group." The CEO suggests talking to Dr. Greedly before running up a big Snooper & Grill legal bill. "Maybe, Greedly can point to reputable authority supporting the proposition that these services were medically necessary," the CEO adds, "and, then, we can shut this thing down."

Snooper & Grill would prefer to gather the relevant documents and interview other nurses and technicians, but they acquiesce in the GC's request that they first talk to Dr. Greedly. Because you know Dr. Greedly, you are asked to call him and set up the interview. After reaching Dr. Greedly, you explain that there has been a complaint that he has provided medically unnecessary surgical services at Oz and that the hospital's compliance program requires a follow-up inquiry to ascertain whether the allegations have merit. You add that Snooper & Grill have been retained so that the fact of the inquiry and the results thereof will be protected under the hospital's attorney-client privilege. You ask when might be a good time for the interview. Dr. Greedly says that he is extremely busy, but he'll get back to you.

A few days later, Dr. Greedly leaves you a voicemail saying he doesn't have time to be interviewed. Snooper & Grill then write Dr. Greedly a letter describing the need for his interview, but promising to conduct the interview at his convenience and to be as brief as possible. The GC subsequently reports that Dr. Greedly called the CEO complaining that you and Snooper & Grill are impugning his professional reputation, that he is not going to respond to baseless accusations generated by jealous competitors and, if necessary, he will move his patients to another hospital.

The medical staff bylaws

Do the medical staff bylaws require a physician with privileges to cooperate with a hospital's internal fraud and abuse investigation?

Miffed, you consider filing a complaint with the Medical Executive Committee (MEC) against Greedly for obstructing a compliance program internal investigation. You are seeking the suspension of his privileges to practice at Oz. You review the Oz medical staff bylaws. Surprisingly, there are no references to the hospital's code of conduct or compliance program in the bylaws. There is a section entitled "Basic Responsibilities of Medical Staff Membership," which sets forth 16 categories of enumerated duties that members are required to perform. These enumerated duties do not require that members abide by the Oz code of conduct, receive education and training on fraud and abuse issues, or cooperate with a hospital internal fraud and abuse investigation. Medical staff members are required to abide by "the lawful ethical principles of the State Medical Society or the member's professional association," and to provide patients with the quality of care that meets the medical staff's professional standards. Staff are also required to disclose certain events to Oz's CEO within a prescribed time period, including the filing of charges or the commencement of a formal investigation of such member by any federal or state law enforcement or health regulatory agency, or exclusion from participation in federal health care programs.

Despite your lofty title, Snooper & Grill point out that the medical staff bylaws do not authorize you to file a complaint against Greedly. Indeed, only the chief of the medical staff, a Staff department or Committee Chair, the CEO, or the hospital's Board of Trustees may file a "request for corrective action" against a medical staff member.

In short, to seek the suspension of his privileges, you must persuade the CEO to file a complaint with the MEC alleging that Greedly provided medically unnecessary services to Oz patients, that such conduct is both unethical and fails to meet the medical staff's professional standards, and that it possibly endangers the health of Oz patients. You question whether the CEO currently has the stomach for this. Alternatively, you could go to the Compliance Committee of the Board of Directors and see if the Compliance Committee can persuade the full board to file such a complaint. If you are successful, MEC will conduct its own investigation of Dr. Greedly or designate an ad hoc committee of the medical staff to conduct the investigation.

Frustrated, you ponder where to turn while Dr. Greedly continues to perform procedures at Oz.

The hospital compliance program

Among the questions posed by our Oz hypothetical are:

- Should the Medical Staff bylaws require a non-employed, medical staff physician to abide by the hospital's code of conduct?
- When a medical staff member is the alleged code of conduct violator, which body enforces the hospital's code of conduct—the hospital compliance officer and/or Compliance Committee, or the medical staff?
- Should a medical staff member's failure to cooperate (e.g., failure to consent to an interview) during a hospital's internal code of conduct investigation constitute grounds for suspension of his or her privileges?
- Should the compliance officer or the Compliance Committee be able to initiate proceedings under the medical staff bylaws

to suspend a medical staff member's privileges, when he or she either is the alleged violator or fails to cooperate?

Application of the code of conduct

Traditionally, medical staffs were organized and bylaws were adopted principally to ensure that the quality of physician services provided at the hospital met professionally recognized standards of care. Thus, although the bylaws typically are amended periodically, most were formulated and adopted long before the advent of hospital codes of conduct and compliance programs. Many such bylaws contain no reference to the hospital's code of conduct/compliance program. Some require compliance with hospital policies and procedures, but others do not contain any language which might be used to argue that the bylaws indirectly incorporate the hospital's code of conduct or compliance program.

Amending the bylaws to require compliance with the hospital's code of conduct requires medical staff approval and may not be politically popular. To complicate matters further, in certain states, state statutes control the grounds for suspending or terminating medical staff membership privileges.

OIG has recently entered into corporate integrity agreements (CIAs) with several hospitals in which the hospital's active medical staff are expressly included in the definitions of "covered persons" and "relevant covered persons" and, thereby, required to comply with the hospital's code of conduct.[1] Within 120 days of the CIA's effective date, covered persons are required to certify in writing that they have received, read, understand, and will abide by the hospital's code of conduct.[2] Under the CIAs, covered persons are also expected to report suspected violations of federal health care program requirements or violations of the hospital's policies and procedures.[3] The hospitals are required to provide to covered persons one hour of general training on the CIA's requirements, the code of conduct, and those portions of the hospital's policies and procedures that pertain to compliance issues.[4]

The term "relevant covered persons" includes "covered persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any federal health care program."[5] Relevant covered persons are required to receive two hours of specific training on a laundry list of items including:

- Federal health care program requirements regarding accurate coding and submission of claims;
- Policies, procedures, and other requirements applicable to the documentation of medical records;
- The personal obligation of each individual in the claims submission process to ensure that such claims are accurate, and the applicable reimbursement statutes, regulation, and program requirements and directives; and
- The legal sanctions for violations of federal health care program requirements.[6]

Each relevant covered person must certify in writing that they have received the required training.[7]

Should today's medical staff bylaws require the active medical staff to understand and abide by the hospital's code of conduct and its policies and procedures, to receive periodic fraud and abuse compliance training, and to report suspected violations? OIG apparently thinks so.

Who enforces the code of conduct?

Which body enforces the hospital code of conduct when a staff member is the alleged violator—the hospital compliance officer/committee or the medical staff? What if the medical staff member is alleged to have violated pertinent state or federal laws or regulations and is also in violation of the hospital's code of conduct? In other words, what if the staff member's conduct has allegedly caused the hospital to file false claims?

If a code of conduct violation gives rise to hospital criminal, civil, or administrative liability, or requires repayment, the hospital has an obligation to investigate, ascertain the facts, and take appropriate remedial action.

That said, the interface between the enforcement of the hospital's code of conduct and the medical staff's traditional role in governing the conduct of its members raises questions for which there are no easy answers. Which body—the hospital Compliance Committee or the MEC—should determine whether the staff member has violated the code of conduct? What due process rights are accorded the accused staff member? Before having his or her privileges suspended or terminated, is the medical staff member entitled to a hearing, to be represented by counsel, to confront and cross examine adverse witnesses, and to present a defense (i.e., the normal "fair hearing" procedures)? If the MEC is the more appropriate body to adjudicate alleged member violations, does the hospital wait until the MEC has rendered its decision before repaying Medicare, Medicaid, et al?

Certain alleged code of conduct violations (e.g. upcoding) require no medical expertise. Other alleged violations, such as providing medically unnecessary services, do require such expertise, but finding medical staff members willing to serve as adjudicators may be problematic. In such instances, should an impartial hearing officer be retained to decide whether the alleged violator's privileges should be suspended or terminated?

Continued on page 26

According to the *American Health Lawyers Association's* membership rankings, we are now the largest healthcare law firm in the United States.

We achieved this by delivering value and security to our clients every day.

KING & SPALDING

www.kslaw.com

Integrating the hospital compliance program with the medical staff bylaws

...continued from page 25

Although the process may be difficult, the hospital, the chief of the medical staff, and the MEC presumably all have a joint interest in expeditiously resolving alleged code of conduct violations involving medical staff members, particularly where the alleged conduct, if true, may endanger the health of hospital patients.

Grounds for suspension

Should a medical staff member's failure to cooperate with a hospital code of conduct investigation be grounds for suspension of his or her privileges? If a hospital-employed physician refuses to cooperate, his or her employment will likely be subject to termination. Should the same obligation to cooperate, (e.g. meeting with the hospital's lawyers conducting the investigation and turning over any relevant documents) extend to a non-employed medical staff member? Presumably, the vast majority of physicians will cooperate. Should those who do not face the possible suspension of their privileges?

If, as in our hypothetical example, the staff member refusing to cooperate is the alleged violator, the focus will be whether the allegations have merit, and any refusal to cooperate will be secondary. If the evidence indicates that the code of conduct has been violated, the Board of Trustees or the CEO will likely file a complaint under the medical staff bylaws, seeking suspension of the violator's privileges on those grounds.

Whether the refusal to cooperate by a staff member who is not a suspected code of conduct violator should be grounds for suspension is a more difficult question. The non-employed staff member does not have the same legal duty of loyalty to the hospital as his or her employed brethren. At the same time, if the staff member is simply a potential witness whom the hospital needs to interview, what is the principled justification for a failure to cooperate? Ultimately, the answer probably depends upon the circumstances, but such situations present tough choices.

Initiating corrective action

Should the compliance officer or the compliance committee be able to initiate a corrective action proceeding for a medical staff member's failure to cooperate or for a an alleged violation of the hospital's code of conduct? Typical medical staff bylaws allow various individuals and committees to submit a request for corrective action. These include the MEC, the chief of service or department head of the medical staff member, the chief of staff, the hospital CEO, and the hospital board. Should the hospital board's Compliance Committee or compliance officer be authorized to request corrective action? Both of these possible additions to the typical list may create serious political issues for a hospital because, from the medical staff's perspective, these additions will likely increase the number of corrective actions and time-consuming investigations. In addition, if the hospital CEO and board can

already initiate a corrective action, is there really any reason why individuals or committees that report to them, respectively, should also be able to initiate an action? Probably not, as long as the compliance officer or the Compliance Committee has direct access to the Board of Trustees in the event that the CEO is unwilling to act. Presumably, when reasonable grounds exist and given the stakes involved, the compliance officer or Compliance Committee will not find it difficult to persuade the CEO or full board to go forward.

Conclusion

To return now to our hypothetical, while the CEO vacillates about taking on Dr. Greedly, help arrives in the form of a federal grand jury subpoena seeking all hospital documents relating to procedures Dr. Greedly performed at Oz during the past 5 years. Concerned about the hospital's exposure, the CEO pushes for Dr. Greedly's suspension. While protesting his innocence, Dr. Greedly resigns from the medical staff on the advice of his attorney.

Two years later, the hospital learns that the grand jury investigation arose as the result of a *qui tam* action filed by a former Greedly Group physician against Dr. Greedly, the Greedly Group, and the hospital. The US Department of Justice intervenes in the *qui tam* action and, citing the complaints of operating room nurses and technicians, asserts that Oz knew that Dr. Greedly was performing medically unnecessary procedures. On Snooper & Grill's recommendation, Oz settles by paying the U.S. $3.5 million dollars and an additional $250,000 in reasonable attorneys fees and costs to the former Greedly Group physician/whistleblower to resolve the *qui tam* action.

Lest you think this hypothetical too fantastic, consider the *qui tam* action filed by Dr. Christopher T. Mallavarapu against Dr. Mehmood M. Patel, Acadiana Cardiology LLC, and Our Lady of Lourdes Regional Medical Center, in the US District Court for the Western District of Louisiana. Dr. Mallavarapu alleged that Dr. Patel was performing numerous medically unnecessary, improper, and excessive procedures at Our Lady of Lourdes, that he reported his concerns to the hospital, requested peer review panels be established to determine whether Dr. Patel's procedures were medically necessary, and that the hospital took no action.[8]

In August 2006, Our Lady of Lourdes, while denying any liability, paid the US government $3.8 million to resolve allegations that Dr. Patel had performed medically unnecessary angioplasty, angiograms, and stenting procedures at the hospital.[9] It reportedly also paid an additional

Continued on page 28

Update Your HIPAA Training

with Coastal Training Technologies' employee training DVDS, newly updated to cover mandates of the Health Information for Economic and Clinical Health (HITECH) Act.

Each video is less than 20 minutes, and comes with 10 participant handbooks to test comprehension.

To order, visit the HCCA website at www.hcca-info.org, or call 888-580-8373.

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

 ...continued from page 27

$7.4 million to settle a class action brought by Dr. Patel's patients.[10] Dr. Mallavarapu received $760,000 of the government's $3.8 million recovery from Our Lady of Lourdes under the *qui tam* provisions of the Civil False Claims Act.[11]

Like our hypothetical Dr. Greedly, Dr. Patel also performed procedures at a second hospital, Lafayette General Medical Center (LGMC) in Lafayette, Louisiana.[12] In late 2006, Dr. Mallavarapu added LGMC as a defendant in his *qui tam* action.[13] In January 2008, LGMC, while denying any liability, paid the United States $1.9 million to settle this action. In April 2008, LGMC agreed to pay an additional $1.8 million to settle approximately 100 malpractice suits brought by former patients of Dr. Patel.[14] Dr. Mallavarapu received $380,000 of the government's $1.8 million recovery from LGMC.[15]

At the time of the January 2008 LGMC settlement, Donald Washington, then the United States Attorney for the Western District of Louisiana, said:

> Hospital providers like LGMC are not entitled to be paid by federal health plans for medically unnecessary procedures. And they may not simply rely on the representation—or in this case the misrepresentations—of the physicians they allow to practice within their facilities. Providers like LGMC have a separate, independent and on-going duty to review the practices and procedures of the physicians they credential, assess those activities in light of the applicable standards of care, and consistently act in whatever manner is necessary to ensure the medical necessity of procedures and the accuracy and integrity of every claim the hospital submits.[16]

In 2009, after a criminal trial, Dr. Patel was sentenced to 10 years imprisonment, fined $175,000, and ordered to make $387,511.56 in restitution as a result of his conviction for making false claims to federal health care programs and private insurers.[17]

Are hospitals at risk if their medical staff bylaws are not updated to address compliance issues? The Our Lady of Lourdes and LGMC ordeals suggests the answer is Yes. ■

1. See Corporate Integrity Agreements between the Office of Inspector General of the Department of Health and Human Services and: Cornerstone Hospital of Huntington, LLC, at 2 (Feb. 26, 2009), available at http://oig.hhs.gov/fraud/cia/agreements/cornerstone_hospital_of_huntington_llc_02262009.pdf; The Queens Medical Center, at 2 (Apr. 22, 2009). Available at http://oig.hhs.gov/fraud/cia/agreements/queens_medical_center_04222009.pdf; and Regency Hospital Company, LLC, at 2 (Apr. 14, 2009). Available at http://oig.hhs.gov/fraud/cia/agreements/regency_hospital_company_llc_04142009.pdf; The County of San Mateo and San Mateo Medical Center, at 2 (Mar. 26, 2009).Available at http://oig.hhs.gov/fraud/cia/agreements/the_county_of_san_mateo_03062009.pdf.
2. Id. at 5.
3. Id. at 4.
4. Id. at 6.
5. Id. at 2.
6. Id. at 6-7.
7. Id. at 7.
8. See Complaint in United States ex rel. Mallavarapu v. Acadiana Cardiology, Civil Action No. 04-0732, ¶¶ 8-10 (W.D. La. Mar. 25, 2004).
9. See Department of Justice, Louisiana Medical Center to Pay United States $3.8 Million to Settle Allegations of Fraud, Aug. 17, 2006, available at http://www.justice.gov/opa/pr/2006/August/06_civ_554.html.
10. See Richard Burgess: Hospital to settle in case of doctor, The Advocate News, April 5, 2008. Aavailable at http://www.2theadvocate.com/news/17317684.html.
11. See Department of Justice, supra note 9.
12. See Amended Complaint in United States ex rel. Mallavarapu v. Acadiana Cardiology, Civil Action No. 04-0732, ¶¶ 10-12 (W.D. La.).
13. See United States Attorney's Office, Lafayette General Medical Center to Pay $1.9 Million to Settle Fraud Allegations in Connection with Medically Unnecessary Cardiology Procedures, Jan. 11, 2008. Available at http://www.justice.gov/usao/law/news/wdl20080111.pdf.
14. See Burgess, supra note 10.
15. See Leslie Turk, Don't Ask, Don't Tell, Acadiana Business, February 2008. Available at http://www.bluetoad.com/display_article.php?id=23802
16. See United States Attorney's Office, supra note 13.
17. See United States Attorney's Office, Louisiana Cardiologist Sentenced in Federal Court for Performing Unnecessary Medical Procedures, June 4, 2009. Available at http://www.justice.gov/usao/law/news/wdl20090604.pdf.

Compliance Today Needs You!

Every month Compliance Today offers health care compliance professionals information on a wide-variety of enforcement, regulatory, legal, and compliance program development and management issues. To do this we need your help!

We are particularly interested in articles covering compliance concerns involving all segments of the health care industry, including Hospitals, Outpatient services, Behavioral Health, Rehab, Physician practices, long-term care,/homecare/hospice, Ambulatory Surgery Centers, etc.

For details e-mail margaret.dragon@hcca-info.org with your topic ideas, format questions, etc. Articles generally run between 1,300 and 2,600 words; this is a guide, not a limit. **Compliance Today** uses the Chicago Manual of Style. We require footnotes to be 10 or less with references appearing at the end of the article. Please do not use the footnote feature in Word. The author's contact information must be included in the article as well as the article title. Articles should be submitted as a Word document with very limited formatting. Please select a deadline from the list below.

IMPORTANT: For those who are Certified In Healthcare Compliance (CHC), please note that CCB awards 2 CEUs to authors of articles published in Compliance Today.

Upcoming Compliance Today Deadlines:

- May 24
- June 1
- July 1
- August 2
- September 1
- October 4