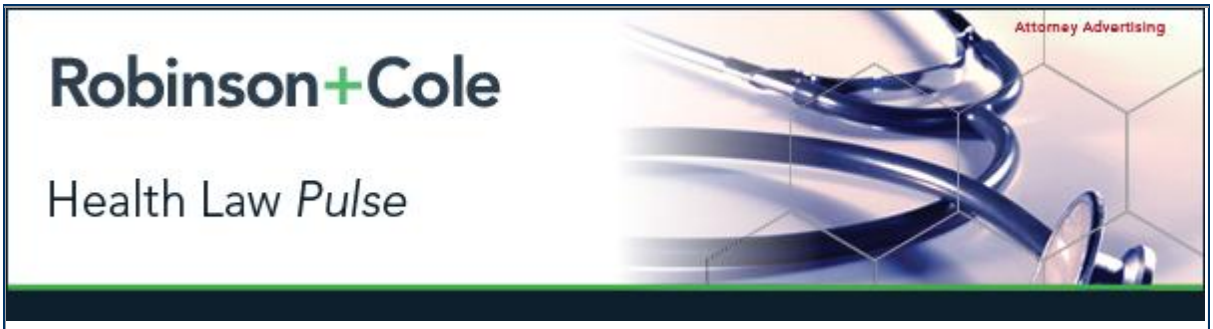

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In This Issue

U.S. DEPARTMENT OF JUSTICE AND CITIZENS MEDICAL CENTER SETTLE FALSE CLAIMS ACT*QUI TAM* SUIT

On April 21, 2015, the United States Department of Justice (DOJ) announced a $21.75 million settlement with Citizens Medical Center (Citizens), a hospital in Victoria, Texas. The settlement stems from a *qui tam* action filed by several physicians (Relators) who formerly practiced at Citizens. The Relators alleged that Citizens violated the federal False Claims Act by knowingly submitting claims for services rendered in violation of the Stark Law (Stark) and federal Anti-Kickback Statute (AKS). The DOJ subsequently intervened in the lawsuit.

Specifically, the Relators alleged that Citizens engaged in illegal financial arrangements with over 25 physicians from several different specialties. The allegations relating to arrangements with certain emergency room physicians, cardiologists, gastroenterologists, and urologists survived a motion to dismiss.

Emergency Room Physicians

According to the Relators, Citizens allegedly paid illegal bonuses to a group of emergency room physicians that practiced at Citizens in return for referrals to Citizens' Chest Pain Center. The Chest Pain Center allegedly generates substantial revenue from nuclear stress tests performed on patients. According to the Relators' complaint, half of the Chest Pain Center revenue, including revenue from Medicare and Medicaid patients, was paid to referring emergency room physicians as bonuses. The Relators also claimed that the number of Medicare and Medicaid patients treated at the Chest Pain Center significantly increased after Citizens began paying referral bonuses to the emergency room physicians.

Gastroenterologists

Similarly, the Relators alleged that Citizens paid bonuses to gastroenterologists that participated in a colonoscopy screening program for which the physicians and Citizens billed Medicare and Medicaid.

According to the allegations, Citizens described the bonuses as “directorship fees” paid for each day a physician participated in the screening program, even though the directorship required no additional work or responsibility. A hospital administrator allegedly assigned gastroenterologists to participate in the screening program based on the number of patient referrals to Citizens. The Relators claimed that Citizens’ sole purpose for the screening program was to induce physicians to use their services, allowing Citizens to bill Medicare or Medicaid in exchange for bonuses paid to the gastroenterologists.

Cardiologists

The Relators’ complaint further alleged that Citizens paid above fair market value salaries to a group of cardiologists to induce them to refer patients, including Medicare and Medicaid patients, to Citizens for cardiac surgery and other services. Allegedly, the cardiologists’ salaries more than doubled in the first year of their employment with Citizens, and there was no market justification for such an increase. Furthermore, according to the Relators, Citizens lost between $400,000 and $1,000,000 per year on the cardiologists’ office practices but continued to employ the physicians because of the volume and value of referrals they generated. The Relators claimed that, in addition to the above fair market value salary, Citizens also provided the cardiologists malpractice insurance coverage, health and dental insurance, dictation services, advertising services, and below fair market value office rents (as low as $1.12 per square foot).

Urologists

The Relators alleged that Citizens entered into an exclusive contract for lithotripsy services with an entity owned by two urologists under which Citizens paid a fee to the entity for each procedure performed; the entity in turn paid a bonus to the physician who performed the procedure. Citizens purportedly provided office rentals to the urologists (and a third urologist) at below fair market value rates. In return, the urologists allegedly referred all of their patients, including Medicare and Medicaid patients, to Citizens. The Relators also alleged that the urologists would not perform services at the other hospital in Victoria, Texas, and would transfer patients from that hospital to Citizens, where they would perform procedures.

Because this case settled before trial, Citizens did not have an opportunity to establish affirmative defenses to the allegations, such as compliance with applicable Stark exceptions or AKS safe harbors. Although the Relators’ complaint did not proceed to trial or result in Citizens admitting wrongdoing, this case highlights several financial arrangements between a hospital and physicians that are likely to draw close scrutiny from the government and potential *qui tam* relators.

OIG RELEASES COMPLIANCE GUIDANCE FOR HEALTH CARE GOVERNING BOARDS

On April 20, 2015, the Office of Inspector General (OIG) published compliance guidance (Guidance) for governing boards of health care organizations (Boards). The Guidance was developed through collaboration among the OIG, the American Health Lawyers Association (AHLA), the Health Care Compliance Association, and the Association of Healthcare Internal Auditors. The Guidance aims to provide practical tips to Boards on effectively executing their compliance-oversight responsibilities.

The authors of the Guidance recognize that the size of and resources available to health care organizations can vary greatly, and as such, the Guidance is not intended to set any particular standards of conduct. Instead, it provides advice to Boards, described further below.

Expectations of Boards

The Guidance encourages Boards, in executing their compliance-oversight responsibilities, to use publicly available resources as benchmarks for their organizations. For example, Boards should review the Federal Sentencing Guidelines, the OIG’s compliance program guidance, and OIG corporate integrity agreements. Each Board should compare its organization’s compliance program to the recommendations set forth in these resources. Boards should also develop formal plans to stay informed of the rapidly changing health care regulatory environment. This may include attending outside educational programs

or tasking management to create educational programs for the Board. In addition, the Guidance suggests that Boards either add a member that has regulatory, compliance, or legal experience or regularly consult with an individual with such experience.

The Guidance suggests that an organization's compliance program reflect the size and complexity of the organization. According to the Guidance, this means that smaller, less complex organizations may have less formal compliance programs and that Boards will be more involved in their compliance programs; however, the Boards of small organizations are still required to exhibit the same commitment to compliance as larger organizations.

Roles & Relationships

The Guidance recommends that an organization's audit, compliance, legal, risk management, human resources, and quality improvement functions have distinct responsibilities but should cooperate and collaborate with each other as they relate to compliance. In organizations where the compliance officer is subordinate to the legal counsel or legal department, the Board should ensure that each function has a reporting relationship with the Board and executive management (so-called "dotted-line" reporting).

Reporting to the Board

Boards must be kept informed of their organizations' compliance efforts, and to accomplish this goal, the Guidance advises them to regularly receive reports from and hold executive sessions with leadership from the audit, compliance, legal, and other appropriate departments. To encourage open communication from departmental leadership, the Guidance suggests that Boards conduct these executive sessions in the absence of senior management.

The Guidance expects Boards to request reports on compliance investigations, serious issues identified through internal audits, issues reported through a compliance hotline, and any other allegations of material fraud or misconduct. Boards may also establish a risk-based reporting mechanism such that management must report to the Board if certain risk factors are met.

Identifying & Auditing Potential Risk Areas

The Guidance identified the following areas as particularly susceptible to fraud: referral relationships, upcoding, billing for medically unnecessary services, privacy breaches, and quality issues. The Guidance advises Boards to confirm management's consistent review and audit of these areas. It suggests that Boards ask their organizations how they are addressing additional risks posed by newer payment models, such as bundled payments and value-based purchasing. The Guidance recommends that Boards use publicized compliance problems at other organizations as occasions to question management on whether their organization has controls in place to minimize the risk of similar misconduct. When conducting risk assessments, the Guidance suggests that Boards use publicly available information, such as disclosures under the federal Physician Payments Sunshine Act or data on health outcomes and quality measures, to compare their organization against peer organizations.

Encouraging Accountability & Compliance

The Guidance recommends that Boards encourage a culture of organizational compliance by using objective compliance-related measures to assess employee performance in promoting and adhering to the organization's compliance responsibilities. The Guidance also reminds Boards that it is the OIG's position that health care organizations have a responsibility to disclose violations of law that occur within the organization. To that end, the Guidance urges Boards to evaluate whether their organizations have processes that encourage employees to raise compliance concerns without fear of retribution.

Conclusion

While the Guidance does not stipulate particular courses of action that Boards must adopt, it does stress that they must play an active role in carrying out their compliance-oversight responsibilities. Board members may want to closely review the Guidance for ways to improve their organization's compliance

program.

OFFICE OF NATIONAL COORDINATOR UPDATES PRIVACY AND SECURITY GUIDE

The Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) recently released an updated version of its Guide to Privacy and Security of Electronic Health Information (Guide). The Guide is meant to assist health care providers, particularly those practicing in small organizations, in integrating and complying with federal health information programs and related privacy requirements, including the Health Insurance Portability and Accountability Act (HIPAA) and the Medicare and Medicaid Electronic Health Records Incentive Programs (Meaningful Use Programs).

The Guide provides a broad overview of the HIPAA Privacy, Security, and Breach Notification Rules and useful guidance on a range of topics, including, but not limited to (1) identifying business associates, (2) patients' access to their protected health information (PHI), (3) requirements related to the use and disclosure of PHI and breach notification, and (4) safeguards and security policies and procedures. The ONC offers tips to health care providers on complying with the HIPAA Privacy and Security Rules while satisfying the Meaningful Use Programs' core objectives. The Guide also offers a list of questions that providers can ask when working with an electronic health record (EHR) vendor to assist them in complying with HIPAA's Security Rule.

The Guide also includes a new chapter on implementing a security management process, which is required by HIPAA. In addition, it includes a sample seven-step approach to assist covered entities and business associates with implementing such a process and meeting the Meaningful Use Programs' privacy and security requirements. The steps include further details such as specific action items and tips for implementation. For example, the ONC provides a list of the types of records providers should retain to document the implementation of their security management processes, which includes a security risk analysis report, EHR audit logs, and a risk management action plan. The Guide also sets forth examples of how providers can mitigate risks presented by office-based and cloud-based EHRs and online patient communication.

The Guide gives providers another resource to help navigate the increasingly complex world of health information technology and may especially be useful for small physician practices and other organizations with limited resources.

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