

Health Care Compliance

LETTER

March 19, 2013
Volume 16, Issue 2
Health.WoltersKluwerLB.com

INSIDE THIS ISSUE

- 1 On The Front Lines**
SUITS AND SCRUBS AVOIDING ORANGE JUMPSUITS™
Volume III: Earning and Keeping the Trust
- 5 Health Care Reform**
CMS releases rules for premium stabilization, risk adjustment, and loss ratios
CMS proposes changes for qualified health plan enrollment in the SHOP
- 6 HIPAA**
Wrongful termination claims of a medical records manager remanded to state court
- 7 Health IT**
Management problems block integration of EHR between VA and DoD
- 8 Fraud and Abuse**
Physician's 5-year exclusion from Medicare based on criminal convictions upheld
- 8 False Claims Act**
Lack of proper allegations prevents Medicare beneficiary from proceeding
Qui tam relator fails to sufficiently allege FCA violation by drug companies
- 9 Quality of Care**
Independent pharmacies use PSAOs to work with third-party payers
Health care delivery improved under PPACA: CMS
- 11 EMTALA**
Magistrate recommends dismissal of hospital's indemnification request
- 12 In The News**

■ ON THE FRONT LINES

SUITS AND SCRUBS AVOIDING ORANGE JUMPSUITS™

Volume III: Earning and Keeping the Trust

By Allan P. DeKaye, MBA, FHFMA and Gregory J. Naclerio, JD

In a networked world, trust is the most important currency.

*Eric Schmidt, University of Pennsylvania
Commencement Address, 2009*

As Executive Chairman of Google, Eric Schmidt would need to know something about trust and how his company is viewed by its subscribers, government and competitors. Healthcare is clearly a networked industry and viewing these organizations, in particular, not-for-profit (“NFP”) hospitals and health systems, from the patients’, government’s, and competitors’ vantage point is no less a challenge. “Trust” is one of the hallmarks of healthcare. Patients trust their doctors to diagnose their ills; doctors trust that hospitals will have cutting edge equipment and motivated staffs; payers trust hospitals to provide medically necessary services and bill them appropriately. When hospitals breach the trust to bill payers for medically necessary services actually rendered, government steps in to level the playing field. Both the federal and New York State governments have been pushing hospitals to develop and implement effective and meaningful compliance programs.¹

However, having a “compliance plan” means precious little if the program is not monitored and/or effective. Government takes the position expounded by President Harry Truman who proudly said; “The buck stops here,” and so it is with compliance and the board of trustees.

It's More than Just a Matter of Trust

To be selected as a trustee of a community NFP, be it a hospital or other community service organization, is an honor. Your colleagues on the board are community leaders, big contributors or friends of the executive director. You get introduced at dinners, your name goes on the NFP website and you get to network with other “movers and shakers” in your community. You go to board retreats at nice locations and enjoy dinner—maybe even cocktails—after board meetings. Life is good. While you get the board agenda and minutes of the prior meeting generally a week in advance of the regularly scheduled board meeting, who has time to read the ½ inch thick volume of material? Besides, there’s always one member on the board who has the time to read all that stuff and contributes a lot, so it must be okay. Besides, we all trust the executive director.

A thought process such as that set forth above is not only a recipe for disaster with respect to the NFP, but could also be a disaster for you personally. Under New York State law, a trustee's duty of care involves discharging "the duties of their respective positions in good faith and with that degree of diligence, care and skill which ordinary prudent men would exercise under similar circumstances in like positions."² A trustee has three major responsibilities:

- Duty of care.
- Duty of loyalty.
- Duty of obedience to the NFP's mission.

The duty of loyalty (e.g., avoiding conflicts of interest) and obedience to the mission of the entity are generally met if the duty of care test is met. The duty of care generally arises in two areas: (a) the "decision making function" where the board is presented with a specific proposal (e.g., to expand the number of operating rooms or commence a new service line, etc.), or (b) the "oversight function" where the board makes sure corporate executives are carrying out their management responsibilities, and are complying with the law. In discharging their duty, trustees, acting in good faith (i.e., the duty of care) may rely on information, reports, statements and financial data prepared by:

- Employees of the entity whom the trustee believes is "reliable and competent" in the matter presented.
- Legal counsel, accountants and others as to matters which the trustee believes to be within such person's professional expertise.
- Committees of the board in which the trustee has confidence.

If a trustee acts in good faith and with due care, the statute provides the trustee "shall have no liability" by reason of being a director.³ Clearly, a trustee cannot just sit passively and accept the information provided. A trustee has to use the same type of judgment in the affairs of the NFP that a prudent person would exercise if that mythical person sat on the board.⁴

As each situation involving an NFP board's obligations is unique, no bright line rules can be provided. However, there are signs that a board member is not doing his/her job. They include:

- Do board members come to the meetings prepared to discuss agenda items?
- Does the board usually "rubber stamp" management recommendations with little or no discussion?

- Does the board have an audit/compliance committee, chaired by an independent board member (one not employed by the NFP)? Similarly, do independent trustees chair all other key committees (e.g., performance improvement, finance, etc.)?
- Does the board meet from time to time in executive session?
- Is the majority of the board "independent"?
- Are "quick revenue producing" opportunities, presented and pressed for by the administration, agreed to without careful consideration of the consequences?
- Does the board meet with the NFP's outside auditors in executive session and make it clear that the auditors work for the board and not administration?
- Does the board have access to independent legal counsel when necessary?

We cannot tell you that you are serving on a board that is not doing its job. However as the old saying goes, "You will know it when you see it!" If you "see it," get the board changed or...Get Out! The checklist shown above is not meant to suggest that most boards will exhibit these shortcomings. But there have been some egregious examples of the failure of board oversight in many reported high profile healthcare fraud and abuse cases that should sound the alarm, and raise the question—"where was the board?"

Hear No Evil, See....

There's hardly a day that goes by without a newspaper or trade journal publishing an account of healthcare fraud and abuse. The federal government uses its "bully pulpit" in the form of daily email updates and alerts on topics ranging from improving the health of the nation to notifying the public of the indictment, arrest, conviction or recovery of ill gotten gains received by defrauding the Medicare and Medicaid programs, courtesy of the U.S. Department Justice and other arms of the federal law enforcement establishment. (See, <https://oig.hhs.gov/fraud/tab>). Surely, these missives should have gotten the attention of boards of trustee members, if only to ask and implore hospital administration, "Don't let this happen to us!"

With so many areas to safeguard, the trustees need to continually ask themselves individually and collectively: "Where is the organization's vulnerability, and how is it being safeguarded?" The issues range from clinical to financial—and can involve

Health Care Compliance LETTER

Senior Managing Editor
Nicole Stone, JD, MBA
Coordinating Editors
Harold M. Bishop, JD
Sarah E. Baumann, JD

CCH Washington Bureau
Newsletter Layout
Kathie Luzod

Requests for information about article submission and comments from readers are welcome and should be directed to Susan Smith at susan.smith@wolterskluwer.com, Tel. 847-267-2780, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

Health Care Compliance Letter is published electronically 6 times a year by Wolters Kluwer Law & Business, 4025 W. Peterson Avenue, Chicago, IL, 60646. Published in U.S.A. ©2013 CCH Incorporated. All rights reserved.

No claim is made to original government works; however, the gathering, compilation, and arrangement of such materials, the historical, statutory and other notes and references, as well as commentary and materials in this Product or Publication are subject to CCH Incorporated's copyright.

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is sold with the understanding that the publisher is not engaged in rendering legal, accounting or other professional service. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

For more information about the Health Care Compliance Portfolio, please visit our online store at WoltersKluwerLB.com.

wrongdoing at every level of an organization. A smattering of headlines suggests that the industry may be beyond the tip of the iceberg with the tipping point already having been breached by many institutions.

Let's look at several examples: The first case involves the former director of urology at the Allen Pavilion of New York Presbyterian Hospital. The doctor was sued, along with Columbia University and New York Presbyterian, in a *qui tam* lawsuit in which the Justice Department joined. The doctor, who treated mostly patients with prostate cancer, also ordered medically unnecessary urine flow tests for all of his patients. He also billed Medicare for more procedures than he was physically able to perform in one day. Specifically, in one day he billed Medicare 17.3 hours—on top of what he billed other carriers—far exceeding the billing of his peers. In this case, the government alleged Columbia and New York Presbyterian knew about his false billings and “did nothing to stop it” after an internal inquiry stated it found “alarming compliance issues” with the doctor. The doctor, Columbia and New York Presbyterian settled the *qui tam* suit for \$995,000.

“We cannot tell you that you are serving on a board that is not doing its job. However as the old saying goes, “You will know it when you see it!” If you “see it,” get the board changed or... Get Out!”

The question arises: Where was the board that was ultimately responsible for the compliance plan? The government alleged that the hospital “did nothing to stop” the improper billing even when the internal inquiry showed “alarming compliance issues.” What was the board’s oversight function when it appeared that the hospital was overbilling? Did they abdicate that responsibility to the administration? The question that the board had to answer was “How could you have let this happen?” That’s not a question a lot of trustees would like to answer.

In North Carolina, WakeMed, an 870-bed not-for-profit healthcare system, sought to settle an allegation that the hospital billed Medicare for more expensive inpatient care when doctors ordered patients to be treated as outpatients. A deferred prosecution agreement with the federal government was predicated on the system paying back \$8 million and agreeing to a 48-page corporate integrity agreement. More interestingly, Federal District Court Judge Boyle noted and was critical of

the absence of any board member or senior administrator at the first hearing to obtain the court’s approval of the settlement. At the second hearing, the board president was seated at the defense table. Do you think Judge Boyle got across the point that it’s the board who is ultimately responsible?

Also in New York, the arrest and conviction of the President of Medisys Health Network (a three hospital system) caused the New York State Governor to address the board’s apparent lack of supervision. Specifically, reference was made for sanctions including revocation of the provider’s Medicaid agreement if the provider failed to have a satisfactory compliance plan in effect after being warned.

Although the focus on the MediSys Health Network case emanated from the conviction of its former CEO for bribery, a recent report that one of its hospitals now faces more than 100 lawsuits related to the quality of care being rendered raises heightened concerns about the trustee’s duty to the “mission,” which almost always is the rendering of quality care to patients.⁵ If patients, as consumers, are to trust that the hospitals they go to will be providing quality care, then there was justifiable concern when a “Consumer Reports analysis (February 2012) found that New York City hospitals performed poorly in patient safety ratings compared to the rest of the nation.”⁶ With federal

and state hospital rankings measuring mortality, quality, patient safety and satisfaction, boards should be examining how their organizations are performing (if they haven’t already done so), in order to truly fulfill the “duty to care.”

If the mission really matters, then trustees also need to be concerned about the levels of financial assistance being given at their institutions. There is a growing concern that the case where an Illinois hospital lost its tax exempt status because its levels of financial assistance were deemed insufficient is a formula that can and will be replicated elsewhere. A February 2012 study released by the Community Service Society (CSS) was critical of hospitals generally failing to meet the requirements of New York State’s Indigent Care Pool (ICP) and Hospital Financial Assistance Law (HFAL).

Citing concerns for the 2.8 million people in the state who don’t have health insurance, the report raises concerns about how hospitals receive funding to offset uncompensated care from the ICP, and yet seem to fall short in terms of approved applications for financial assistance, while reporting large amounts of bad debt.⁷ With many states and other

Health Law Advisory Board

Allan P. DeKaye, MBA, FHFMA
DeKaye Consulting, Inc.

Fay A. Rozovsky, J.D., M.P.H.
President, Rozovsky Group

Thomas Coons, JD
Ober | Kaler

Ericka Adler, JD
Kamensky Rubenstein

Colin Roskey, JD
Alston + Bird

Robert L. Roth, JD
Hooper, Lundy & Bookman

Andrew Ruskin, JD
Morgan Lewis

Kristine Salcedo, JD
Cancer Centers of America

organizations conducting studies about CEO compensation levels (a subject that has already garnered Congressional inquiry) and the amount of financial assistance offered (read charity care and not necessarily the overly broad “Community Benefit Expense” category), boards would be well advised to examine this relationship to ensure that any inverse relationship is defensible and consistent with its mission.⁸

The Last Resort

Make no mistake about it—these problems aren’t localized to New York or North Carolina; they are occurring every day in abundance throughout the country. But the premise of the *Suits and Scrubs* series has been to point out where the weaknesses in the healthcare system exist, and to what extent human frailty plays a part in committing healthcare fraud. The safeguard of last resort is the trustee whose fiduciary responsibility is to provide another and perhaps final layer of review.

Maybe the resignation of the Prime Healthcare Services (California) president and CEO because of accusations of up-coding is proof of a health system policing itself.⁹ However, the assistant administrator of a Houston hospital either didn’t get out in time (or maybe never intended to), and was indicted for an alleged role in a \$116 million Medicare fraud scheme concerning the receipt of kickbacks from patient recruiters and billing for medically unnecessary services.¹⁰

Maybe the internal safeguards are working in some places. In Maryland, the president and chief administrative officer of Dimensions Healthcare System, who was under an internal investigation for alleged kickbacks, resigned after 18 months on the job. While the case has striking similarities to the MediSys Health Network allegations of bribery and official misconduct, in the Dimensions case the health system was not the subject of the federal investigation.¹¹ However, given the large investments that healthcare systems have and will be making regarding purchasing electronic medical records systems, integrated information systems, and improved purchasing practices, the high dollar value of these various contracts raises the stakes for potential misdeeds. The need for board oversight involvement in awarding these large contracts could not be greater.

Unfortunately, there isn’t any data or repository to suggest how well internal safeguards are working, and whether the board’s oversight was effective. And unlike the Federal Aviation Administration that reports on “airline near misses and other mishaps,” the industry doesn’t track how many problems or schemes were disrupted, prevented or identified because of the due diligence and duty to perform that is carried out daily by administration and boards. We are also reminded that federal and state officials don’t always report on all attempted acts of terror that were thwarted. But we are constantly reminded that data breaches continue to occur, oftentimes at a somewhat alarming rate. Perhaps boards of

trustees need additional tools at their disposal to fulfill their fiduciary responsibilities.

Even though most municipal and state jurisdictions have their own police forces, it’s interesting to note that many of the district attorneys in these locales have their own investigative staff. While many are current or former police officers, their separate reporting lines ensure a level of independence that allows prosecutors to make their cases. Even committees of Congress have their own staffs to conduct research, reviews and analysis. Maybe it’s time for boards to be afforded some level of investigative support that would enhance their safeguarding mission. And while this will be an added healthcare expense, it may pale in comparison to the fines and penalties that may be avoided, if exposure issues are detected and preventive actions implemented as a result of more proactive board involvement.

Former DHHS Inspector General, Richard Kusserow, discusses the possibility that hospitals and healthcare systems consider outsourcing their compliance programs. This could range from a compliance officer to the entire compliance apparatus. Although he may now have a vested interest in promoting outsourcing as he is the CEO of a company that provides this service, it raises the prospect of creating a greater sense of independent assessment to prevent or mitigate problem situations.¹² In the same way a home buyer would seek an outside engineering report on the value and worthiness of a home, boards need to ask themselves the question: “Are we doing we all we can to protect the organization?”

We do know the U.S. Department of Justice has recovered \$4.1 billion in healthcare fraud in FY 2011, and \$4.2 billion in FY 2012.¹³ With numbers that high, there seems to be a lot of work left to do. With more active board involvement, and the potential of adding tools to its “oversight arsenal,” the path to prevention should be a lot easier and more effective—and as a result, a good measure of trust restored. ■

Suits and Scrubs Avoiding Orange Jumpsuits™ is a registered trademark of Allan P. DeKaye and Gregory J. Naclerio. This article is the third one by the authors in the Suits and Scrubs series.

© 2013 by Allan P. DeKaye and Gregory J. Naclerio. All Rights Reserved. Reprinted with permission of the authors.

For more information about the article, or presentations by the authors, please contact:

Allan P. DeKaye, MBA, FHFMA, is President and Chief Executive Officer of DEKAYE Consulting, Inc. His firm assists healthcare clients with financial, compliance and operational issues. He is a frequent speaker at national conferences, and is author/editor of *The Patient Accounts Management Handbook* (Aspen). Mr. DeKaye also is a member of the CCH Health Care Compliance Editorial Advisory Board. For more information: call: (516) 678-2754; write: dkconsult1@aol.com, or visit: www.dekaye.com.

Gregory J. Naclerio, JD, is a Martindale Hubbell AV pre-eminently rated Of Counsel at Ruskin Moscou Faltischek, PC, where he is a member of the Health Law Transactional and Health Law Regulatory Departments and co-chair of the White Collar Crime & Investigations Group. Mr. Naclerio previously served as the Director of the Long Island Regional Office of the Deputy Attorney General for Medicaid Fraud Control. He is also a Certified Fraud Examiner, and has authored many articles on white-collar fraud issues and is a frequent lecturer on this topic. For more information: call: (516) 663-6633; write: gnaclerio@rmfpc.com, or visit: www.rmfp.com.

Endnotes

- ¹ N.Y. Social Service Law, 363-d and 18 NYCRR 521. See, also New York State Dept. of Health, *Compliance Program Guidance for General Hospitals*.
- ² Not for Profit Law § 717.
- ³ *Id.*, § 717 (b).
- ⁴ Corporate Responsibility and Corporate Compliance: A resource for Health Care Board of Directors, www.oig.hhs.gov.
- ⁵ K. Cheung, "Hospital faces 100+ lawsuits; NYC plagued with

poor patient safety." FierceHealthcare (3/1/12) (online at: <http://www.fiercehealthcare.com/print/node/67757>).

- ⁶ *Supra*.
- ⁷ "Incentivizing Patient Financial Assistance: How to Fix New York's Hospital Indigent Care Program." Community Service Society (New York, NY). February 2012 (available at: www.cssny.org).
- ⁸ A. DeKaye and G. Naclerio, "Suits and Scrubs Avoiding Orange Jumpsuits," CCH Healthcare Compliance Letter, August 16, 2011, p. 6.
- ⁹ K. Cheung, Prime Healthcare CEO resigns amidst upcoding accusations." FierceHealthcare (2/24/12) (online at: <http://www.fiercehealthcare.com/print/node/67563>).
- ¹⁰ U.S. Department of Justice, Press Release, 2/8/12.
- ¹¹ K. Cheung-Larivee, "Dimensions president resigns after internal investigation of kickbacks." FierceHealthcare (2/14/13) (online at: <http://www.fiercehealthcare.com/node/67703/print>).
- ¹² Kusserow, R. P., "Is Outsourcing Your Compliance Program and Option? Found at the Strategic Management Services, LLC web site at: www.strategicm.com.
- ¹³ U.S. Department of Health and Human Resources Press Release, 2/11/13, "Departments of Justice and Health and Human Services announce record-breaking recoveries resulting from joint efforts to combat health care fraud."

HEALTH CARE REFORM

CMS releases rules for premium stabilization, risk adjustment, and loss ratios

CMS has issued a *Final rule* and an *Interim Final rule with comment period* that will implement key aspects of the Patient Protection and Affordable Care Act (PPACA) (P.L. 111-148). The rules involve the market protections for individuals who buy health insurance through the health insurance marketplaces (formerly called health insurance exchanges) and also reduce the risk of "adverse selection" for policy issuers by subsidizing the premiums paid for beneficiaries in poor health.

The *Final rule* provides that the issuer of a qualified health plan (QHP) will calculate the amount of cost reduction that an enrollee will receive based on the information available in the application. The issuer will determine the amount of advance payment of the enrollee's premium tax credit. Payments will be made from the Treasury Department to the issuer to cover the anticipated cost sharing.

Risk adjustment. The rule reduces the incentive for QHP issuers to charge higher premiums in case their estimates of enrollees' costs are too low through a three-phase program of risk adjustment. The risk of costs for each enrollee is scored based on age and current diagnoses. During the first three years, the government will use temporary risk corridors, so that if an enrollee's expenses exceed the estimates by a certain

percentage, it will be entitled to a payment; if enrollees' premiums paid exceed the expenses by a percentage, the amount due to the issuer is adjusted accordingly. A transitional reinsurance program will address this risk until a permanent risk adjustment takes effect. The payments to issuers are referred to as "premium stabilization payments."

User fees, stabilization payments and the medical loss ratio. Issuers will be charged user fees calculated as a percentage of premiums. These fees will be counted as regulatory fees in calculating the medical loss ratio (MLR). The *Final rule* will change the way that premium stabilization payments are treated in calculating the MLR.

Amendments. The amendments to the 2014 Notice of Benefits and Payment Parameters make changes to the calculation of risk corridors so to align them with the single risk pool. They also describe a new methodology for the calculation of an enrollee's cost sharing reduction. ■

CMS Final rule and Interim final rule with comment period, 78 FR 15409 and 78 FR 15541, March 11, 2013, Health Care Compliance Reporter, ¶700,396 and ¶700,395, respectively

CMS proposes changes for qualified health plan enrollment in the SHOP

CMS has announced a *Proposed rule* which would implement §1311(b)(1)(B) of the Affordable Care Act (ACA) [Affordable choices of health benefit plans] by: (1) amending existing regulations regarding the triggering of events and special enrollment periods (SEP) for qualified employees and their families, and (2) implementing a transitional policy for employees' choice of qualified health plans (QHPs) in the Small Business Health Options Program (SHOP). The transitional policy would apply to plan years beginning during 2014. Comments on the proposed amendments will be accepted for 30 days after publication in the *Federal Register*.

Establishment of SHOP Exchanges. Starting in 2014, §1311(b)(1)(B) of the ACA directs each state that chooses to establish an Affordable Insurance Exchange (Exchange) to also provide for the establishment of a SHOP Exchange (SHOP) designed to assist qualified employers in the state who are small employers in facilitating the enrollment of their employees in QHPs that are offered in the small group market. The March 27, 2012, Exchange Establishment Rule (77 FR 18310), which will be modified by the agency's Notice of Benefit and Payment Parameters for 2014 (also contemporaneously published in the *Federal Register* on March 11, 2013) provides the administrative standards for SHOPS. In the Exchange Establishment Rule, CMS established the standards for SEPs for individuals enrolled in an Exchange or SHOP. These standards provided that a SEP runs 60 days from the date of a triggering event.

Proposed amendments. CMS now proposes the amendment of the SEP for the SHOP from 60 days to 30 days for most triggering events, so that it aligns with the SEPs for the group insurance market as established by the Health Insurance

Portability and Accountability Act of 1996 (HIPAA). CMS also proposes that if an employee or dependent becomes eligible for premium assistance under Medicaid or the Children's Health Insurance Program (CHIP) or loses eligibility for either program, this would be a triggering event, and the employee or dependent would have a 60-day SEP to select a QHP.

Transitional policy. The Exchange Establishment Rule also prescribed the minimum functions of a SHOP. These functions include the requirements that: (1) the SHOP allow employers the option to offer employees all QHPs at a level of coverage chosen by the employer, and (2) the SHOP may allow employers to offer one or more QHPs to qualified employees by other methods. Under CMS' proposed transitional policy, applicable to plan years beginning during 2014, a SHOP would have the option of permitting qualified employers to offer their qualified employees a choice of QHPs at a single level of coverage, but would not be required to do so. In addition, federally-facilitated SHOPS (FF-SHOPS) would not be allowed to exercise this option, but would instead be required to assist employers in choosing a single QHP to offer their qualified employees.

CMS believes that this transitional policy will (1) provide needed time to prepare for an employee choice model (i.e., choice among competing QHPs and access for qualifying small employers to the small business health insurance tax credit), and (2) will increase the stability of the small group market while still providing small groups with the benefits of SHOP during the 2014 plan year. ■

CMS Proposed rule, 78 FR 15553, March 11, 2013, Health Care Compliance Reporter, ¶730,193

■ HIPAA

Wrongful termination claims of a medical records manager remanded to state court

The LaPorte Regional Physician Network, Inc. (Network) is entitled to summary judgment on a federal claim made by Diana Lundell (Lundell), a medical records manager that her job termination violated the Health Insurance Portability and Accountability Act (HIPAA). Although HIPAA provides both civil and criminal penalties for improper disclosures of medical information, enforcement of the statute is limited to the Secretary of HHS and the attorney general of a state, the court said. Lundell asserted that the Network violated HIPAA regulations and retaliated against her for complaining about its alleged unlawful conduct. The court noted that retaliation claims have been construed as not arising under HIPAA, but rather as wrongful discharge claims in violation of state law.

Lundell's claims under state law were remanded to state court for resolution.

HIPAA law and regulations. The specific regulation that Lundell alleged was violated by the network, 45 C.F.R. §164.530(g)(2), was promulgated pursuant to HIPAA, and there is no implied right of action under this regulation, the court said. To enforce a federal law, Congress must create a private right of action, the U.S. Supreme Court has said, which it did not do with respect to HIPAA. The court found that every court that has considered the issue of whether HIPAA creates a private cause of action has concluded it does not.

Other claims. Lundell claimed that she performed her job satisfactorily but the Network disagreed. Lundell maintained that the network demoted and then discharged her for complaining about and failing to advance the network's unlawful activities relative to billing and the handling of patient records. Lundell confirmed that her claims also were brought pursuant to Indiana law, the court found.

Lundell claimed that the Network violated I.C. sec. 5-11-5.5-2 by presenting false claims to the state for payment concerning certain Medicaid recipients. She also claimed that the Network violated I.C. secs. 12-15-27 and 16-39-2 relative to the handling of medical records—then wrongfully demoted and terminated her employment because she complained about the Network's alleged unlawful conduct.

Remand. The Seventh Circuit has repeatedly emphasized that, "when all federal claims are dismissed before trial, the district court should relinquish jurisdiction over pendent state-law claims rather than resolving them on the merits," the district court said. This presumption is subject to exceptions that did not apply in this case. In addition, difficult questions of fact and state law remained that had yet to be fully briefed, the court found. The factors of economy, convenience, fairness, and comity favored remanding Lundell's state law claims to state court, the court decided.

Result. The court granted the Network's motion for summary judgment relative to Lundell's federal claim brought pursuant to HIPAA and noted that all other federal claims had been withdrawn or dismissed. The court remanded the remaining state law claims to LaPorte Superior Court for adjudication. ■

Lundell v. LaPorte Regional Physician Network, N.D. Ind., February 20, 2013, Health Care Compliance Reporter, ¶801,784

■ HEALTH IT

Management problems block integration of EHR between VA and DoD

The decision by the Veterans Administration (VA) and the Department of Defense (DOD) to abandon a plan to develop one unified electronic health records (EHR) system for both agencies is unlikely to result in the successful exchange of information, according to the testimony of Valerie C. Melvin before the House Committee on Veterans' Affairs. Melvin, the Director of Information Management and Technology Resources Issues at the Government Accountability Office (GAO), described the management problems that have hindered the departments' efforts to share EHR since they began in 1998.

The need for shared records. An interoperable EHR system is especially necessary to meet the needs of soldiers and veterans because of their mobility among the sites within each agency as well as between the DOD and the VA. In addition to maintaining a complete history of a patient's care, the departments use the EHR systems for decision support.

Past efforts. In 1998, the two departments tried to develop a method to view the data related to common patients through either system. Three years into the project, the GAO found that basic principles of information technology (IT) project planning had not been followed; there were no clear goals or objectives and no detailed plans for design, implementation or testing of the interface. There was no way to make a decision that would bind all parties. After efforts to follow GAO's recommendations faltered, the two departments scaled down the project to allow transfer of patients' data from the DOD to the VA on discharge from the military. This project was completed in 2004.

Further efforts to allow clinicians to share data also were stymied by lack of clearly articulated common goals and planning, as the testimony described at length. The National Defense Authorization Act for fiscal 2008 directed the VA and DOD to develop a jointly operable system by September 30, 2009, and established an Interagency Program Office (IPO), which was to be accountable for both agencies' efforts to meet the deadline. GAO reported that the IPO never developed an integrated master schedule, and control of the budget was still divided between the two agencies.

The Lovell Center. DOD and the VA developed a shared medical center in North Chicago, Illinois, which was to be used by beneficiaries of both agencies and have integrated staff, one governing body and one source of funding. GAO reported that the plan for the IT system was never fully developed; for example, the plan did not specify all of the activities required of the system. Functionalities such as single sign-in were not in place when the facility opened in the fall of 2010. By March 2012, \$122 million had been spent on workarounds, but the two departments could not estimate a final cost.

The unified system. The two departments committed in 2011 to build a single, unified EHR system in order to avoid the continued problems of interoperability. In 2012, they announced that it would be operational in 2017. This is the project that the departments abandoned in February 2013. The VA plans to improve its existing system. The DOD is deciding whether to work with the VA's system or buy another commercial system. ■

GAO Testimony, No. 13-413T, February 27, 2013

Physician's 5-year exclusion from Medicare based on criminal convictions upheld

A district court upheld the HHS Secretary's decision to exclude a physician from Medicare and other federally funded health care programs for five years. The court determined that Gregory J. Salko's misdemeanor convictions were related to the delivery of an item or service under Medicare and that he was subject to mandatory exclusion. The court denied Salko's motion for summary judgment and granted Secretary Kathleen Sebelius' motion for summary judgment.

Background. On June 20, 2009, Salko pled guilty to violating 42 U.S.C. §1320a-7B(a)(2)(ii) by knowingly and willfully causing a false representation of a material fact to be made for use in determining rights to Medicare benefits, and to violating 42 U.S.C. §1302d-6(a)(2) by knowingly obtaining and causing the unlawful disclosure of a patient's protected health information. He admitted that he falsely prepared a progress note for a Medicare patient who had already switched doctors, although he did not submit the bill to Medicare. In May of 2011, the HHS Inspector General excluded Salko from participation in Medicare and other federally funded health care programs for five years, pursuant to 42 U.S.C. §1320a-7, which states, in relevant part, that an individual who has been "convicted of a criminal offense related to the delivery of an item or service" under federally funded health care programs will be excluded. The HHS Departmental Appeals Board (DAB) affirmed the decision and Salko appealed to the district court, alleging that his crime was not "related to" the delivery of an item or service under Medicare and that he was not, therefore, subject to mandatory exclusion.

"Related to" Medicare. At the outset, the court stated that Salko did not appeal the Administrative Law Judge's (ALJ's) finding that his conviction was related to delivery of an item or service under Medicare to the DAB, barring him from raising the issue before the court. However, the court chose to analyze the issue. It determined that Congress' intent to prevent persons from making false statements related to Medicare payments was unambiguous. Because "related to," was not defined in the statute, the court examined the term's ordinary meaning. It determined that the term was interpreted broadly and generally meant to bear some relation to another object or event. The ALJ who initially reviewed the case noted that progress reports, such as the false report that Salko generated, were generally made to support a claim in the event that Medicare audited a provider. Salko would not have made the false progress report had he not intended it for the purpose of determining rights to a benefit of payment under Medicare and essentially admitted to that motive by pleading guilty to the misdemeanor with which he was charged. The district court determined that the HHS Secretary, in upholding the exclusion, acted reasonably.

The court rejected Salko's other arguments, noting that CMS' reinstatement of his billing privileges related only to Salko's failure to report the suspension of his medical license, rather than his criminal conviction. The court denied Salko's motion for summary judgment and granted Sebelius' motion for summary judgment. ■

Salko v. Sebelius, M.D. Pa., February 19, 2013, ¶801,783

Lack of proper allegations prevents Medicare beneficiary from proceeding

Julie Zeman, a Medicare beneficiary, unsuccessfully alleged false claims violations against a hospital because she provided nothing but bills received for certain services on certain dates and did not allege any particular scheme to infer that the hospital actually and knowingly submitted false claims to the federal government. To prevail on her False Claims Act claim, Zeman needed to show that: (1) the hospital made a claim against the United States, (2) the claim was false or fraudulent, and (3) the hospital knew that the claim was false or fraudulent. She did not present any such evidence, therefore her claim was dismissed.

Zeman's experience. Zeman is covered by a Medicare managed care plan administered by third party companies, and underwent foot surgeries at USC University Hospital

on August 25, 2008, April 30, 2009, October 27, 2009, and February 15, 2011. Zeman later received hospital bills that she alleges are improper in two ways: (1) the hospital improperly billed her for post-operative office visits within 90 days of a surgery, in violation of Medicare regulations, and (2) the hospital improperly billed her for medical services that were not provided at any hospital facility. Zeman then filed a qui tam complaint against USC Hospital for violations of the False Claims Act, alleging that the hospital knowingly presented false or fraudulent claims to Medicare and used false records to get the fraudulent claims approved. The government did not intervene.

Allegations. Unfortunately, Zeman did not specifically provide any indication that the hospital knew about the improper

bills. Without at least alleging that the hospital had knowledge of the false claims or was engaged in some fraudulent scheme, Zeman's complaint was dismissed. According to the court, "it is

not enough 'to describe a private scheme in detail but then to allege simply and without any stated reason . . . that claims requesting illegal payments must have been submitted.'" ■

Zeman v. USC University Hospital, C.D. Cal., February 19, 2013, Health Care Compliance Reporter, ¶801,875

Qui tam relator fails to sufficiently allege FCA violation by drug companies

A *qui tam* relator alleging that pharmaceutical companies violated the False Claims Act by promoting off-label uses of their drug failed to allege a false claim with particularity. While the complaint was not barred by the first-to-file rule, a relator must allege with particularity that specific false claims were presented to the government for payment. The complaint did not identify any particular instance in which an off-label prescription for the drug was submitted to a government health program for reimbursement. Therefore, the complaint was dismissed without prejudice.

Background. The defendants, Alpharma, Inc., Alpharma Pharmaceuticals, LLC, King Pharmaceuticals, Inc., and Pfizer, Inc., manufactured and marketed Flector Patch, a topical pain medication. The relator, Jerome Palmieri, who was employed by the companies as a sales representative, alleged that they engaged in a comprehensive scheme to promote the prescription of Flector Patch for off-label uses and in excessive dosages. For example, Palmieri alleged, although the FDA only approved usage of Flector Patch for up to 14 days, the companies promoted a 60-patch, 30-day prescription as the standard prescription. According to Palmieri, by engaging in this conduct, the companies caused false claims to be presented for reimbursement to government health care programs, which generally do not pay for drugs that are prescribed for off-label uses. Palmieri also alleged that the defendants distributed benefits to doctors who were high prescribers of Flector Patch, in violation of the Anti-Kickback Statute (42 U.S.C. §1320a-7b). The pharmaceutical companies filed a motion to dismiss.

First to file. The court found that the first-to-file rule, codified in 31 U.S.C. §3730(b)(5), did not bar Palmieri's complaint. Although another case making the same allegations against Alpharma was filed four days earlier, the relator in that case voluntarily dismissed her case in August 2011, after the government declined to intervene, and Palmieri filed his amended complaint in October 2011, after the voluntary dismissal. Therefore, the first-filed *qui tam* action was no longer "pending" when Palmieri filed his amended complaint.

Pleading with particularity. The court did, however, dismiss the complaint on the basis that Palmieri failed to plead particular false claims. The parties noted a circuit split on the issue of how specific a complaint's allegations of false claims must be, but the Fourth Circuit expressly ruled in *United States ex rel. Nathan v. Takeda Pharmaceuticals of North America, Inc.*, that a relator must allege with particularity that specific false claims actually were presented to the government for payment. While the complaint contained many details of the marketing scheme, it failed to allege the details of the submission of any Flector Patch prescription to a government entity for payment. Accordingly, the court dismissed the complaint without prejudice for failure to state a claim upon which relief could be granted. ■

United States ex rel. Palmieri v. Alpharma, Inc., M.D. Md., March 5, 2013, Health Care Compliance Reporter, ¶801,800

■ QUALITY OF CARE

Independent pharmacies use PSAOs to work with third-party payers

Independent pharmacies are using pharmacy service administrative organizations (PSAOs) to help achieve administrative efficiencies, according to a report from the Government Accountability Office (GAO). In 2011 and 2012, the GAO identified 22 PSAOs operating in the United States. PSAOs primarily negotiate contracts with third-party payers on behalf of pharmacies. In addition, they provide communication about reimbursement policies of third-party payers, as well as regulatory and statutory requirements to independent pharmacies.

Independent pharmacies. In 2011 and 2012, the GAO reported that there were approximately 21,000 independent pharmacies in the United States. There are five classifications of pharmacies: independent, chain, franchise, government, or alternative site, such as a physician's office. Independent pharmacies are retail pharmacies with store-based locations, often located in rural and underserved areas, that dispense prescription and non-prescription medications to consumers. Independent

pharmacies account for 34 percent of all pharmacies and provided 17 percent of the \$266 billion of prescribed medications in 2010, the GAO said. Independent pharmacies primarily purchase drugs from wholesalers and account for 15 percent of wholesalers' business, according to the GAO.

PSAOs. The National Council for Prescription Drug Programs' database indicates that 18,103 independent pharmacies are associated with a PSAO. PSAOs can have anywhere from 24 to 5,000 pharmacies under contract with most PSAOs having fewer than 1,000 pharmacies as customers. The GAO found that PSAOs are regional in nature with most not operating on a nationwide basis. Of the 22 PSAOs identified by the GAO, 9 were owned by drug wholesalers, 6 were owned by independent pharmacy cooperatives, 4 were owned by group purchasing organizations, and 3 were owned by other entities. One wholesaler stated that it formed its PSAO because pharmacies were looking for this type of service.

PSAO services. Third-party payers now pay for 80 percent of all prescriptions. This is a dramatic change from 30 years ago, when payments from consumers accounted for the largest portion of expenditures on prescription medication, according to a report from the Agency for Healthcare

Research and Quality. It is this shift that resulted in the rise of PSAOs, according to the GAO. PSAOs negotiate contracts, provide communication and offer help-desk services to pharmacies. Specifically, PSAOs (1) negotiate reimbursement rates, (2) establish payment terms, (3) negotiate when audits of pharmacies by third-party payers will occur, (4) provide price updates and (5) conduct appeals. PSAOs indicated to the GAO that audits and reimbursement rates were of a particular concern to pharmacies. A number of PSAOs provide central payment and reconciliation services, as well. PSAOs often require independent pharmacies to participate in all contracts that they negotiate with third-party payers or pharmacy benefit managers (PBMs). Some allow pharmacies to pick and choose from existing contracts.

Negotiations. Over half of the PSAOs interviewed by the GAO reported having little success in modifying terms of contracts as a result of negotiations. The use of standard contracts by PBMs and third-party payers and the consolidation of PBMs with control of larger markets has diminished the ability to negotiate rates, according to the GAO. PBMs, however, said that there were still opportunities to negotiate, especially if there was large number of pharmacies in a PSAO or if the pharmacies were concentrated in one particular area. ■

GAO Report, GAO-13-176, January 1, 2013

Health care delivery improved under PPACA: CMS

The delivery of health care is markedly different today than three years ago, prior to the passage of the Patient Protection and Affordable Care Act (PPACA) (P.L. 111-148), according to Jonathan Blum, Deputy Administrator and Director of the Center of Medicare at CMS. Jonathan Blum testified before the Senate Finance Committee on February 28, to what he characterized as significant impacts and improvements in health care delivery and quality due to reforms put into place by PPACA. Blum testified that a distinct focus has been put on avoiding costly mistakes and hospital readmissions, keeping patients healthy, rewarding quality instead of quantity, and creating the health information technology infrastructure that enables new payment and delivery models to work. So far, data shows that PPACA might just be successful in what it set out to do.

Slower spending. In the past three years, health care spending grew more slowly than in any other year in the past 51. Medicare spending per beneficiary grew just 0.4 percent per capita in fiscal year 2012, continuing the pattern of very low growth in 2010 and 2011. Medicaid spending per beneficiary also decreased 0.9 percent in 2011, compared to 0.6 percent growth in 2010. Family premiums for employer-sponsored insurance have remained consistent, as well; the average annual increase was 6.2 percent from 2004-2008, 5.6 percent from 2009-2012, and 4.5 percent in 2012 alone. CMS estimates

another \$2.1 billion in savings as a result of PPACA's medical loss ratio policy and its strengthened rate review program.

Health outcomes. CMS credits provisions of PPACA with a showing of better health outcomes, exemplified by a decrease in hospital readmission rates. Incentives to reduce readmissions, such as financial penalties that Medicare imposes on hospitals with high readmission rates, as well as extra funding and incentives for hospitals and outpatient providers to do a better job of coordinating care for patients after they head home seem to be contributing toward better health outcomes. The nationwide rate of hospital readmissions of Medicare patients within 30 days of discharge declined to about 17.8 percent by last November after spending five straight years at 19 percent and likely for decades prior to that. CMS noted this translates to about 70,000 fewer readmissions in 2012.

Also, now that Medicare beneficiaries have access to information on health outcomes and health care quality, they have become educated "shoppers" and can use that knowledge when looking for or enrolling in a Medicare Advantage plan. According to CMS, more seniors are able to choose from a broader range of higher quality Medicare Advantage plans, and more seniors have enrolled in these higher quality plans, as well. Since PPACA, enrollment in Medicare Advantage has increased by 30 percent and premiums have fallen by 10 percent.

Paying for value. Reforms put into place by PPACA are enabling the public to pay for value in health care, not simply the quantity of care provided, while patient safety is promoted and care is better coordinated. This is due in part to successful implementation of programs such as the Hospital Value-Based Purchasing Program and the Hospital Readmissions Reduction Program. CMS has also implemented a number of reforms to crack down on fraud and ensure that payments are accurate. According to CMS, Medicare is effectively becoming “an active purchaser of high-quality, affordable care.”

Better care and safety. Many other programs put into place by PPACA are also showing improvements in health care delivery. CMS has undertaken several efforts to promote better care and improve patient safety, focusing on programs that assist health care providers in delivering coordinated, high quality care to their patients. Electronic health records, Partnership for Patients, Strong Start for Mothers and Newborns, Hospital Compare, and the Community-Based Care Transition Program are just a few of the programs demonstrating success with marked improvements in care. Blum commented “These programs not only will help save money for patients and taxpayers, but we believe they will save lives.”

CMS’ Center for Medicare and Medicaid Innovation, charged with testing innovative payment and service delivery models to reduce expenditures in Medicare, Medicaid, and CHIP, and at the same time, preserving and enhancing quality of care is already engaged in projects with more than 50,000 health care providers to improve care. The Innovation Center is focused on finding ways for continuous quality improvement.

Cost reduction. New programs are also in place to reduce unnecessary costs. CMS is working to implement and expand competitive bidding for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), which enables the Medicare program to pay a fairer and more accurate price for equipment used by beneficiaries. The CMS Office of the Actuary estimated that the program would save the Medicare Part B Trust Fund \$26.2 billion and beneficiaries \$17 billion between 2013 and 2023.

Another way to significantly reduce costs is through the elimination of fraud and abuse. PPACA strengthened CMS’ ability to step up efforts to prevent and detect fraud and crack down on individuals who attempt to defraud Medicare, Medicaid, and CHIP. This has resulted in a record level of recoveries—\$4.2 billion in fiscal year 2012—and a record return on investment—\$7.90 for every dollar invested. CMS estimates that the total recoveries over the past four years were \$14.9 billion compared to \$6.7 billion over the prior four years. ■

CMS Testimony, February 28, 2013

■ EMTALA

Magistrate recommends dismissal of hospital’s indemnification request

A hospital may not obtain common law indemnification from individual physicians for amounts the hospital may be required to pay a patient for violations of the Emergency Medical Treatment and Active Labor Act (EMTALA) (42 U.S.C. §1395d). A magistrate in the District Court of Tennessee recommended that Metro Nashville General Hospital’s (MNGH) complaint for indemnification against two doctors and the corporation they work for be dismissed with prejudice. The magistrate noted that the Sixth Circuit has held that EMTALA does not authorize a private right of action in favor of patients against physicians. Further, EMTALA’s legislative history precludes private suits against individuals. The magistrate held that if MNGH were allowed to recover indemnification from the doctors, the hospital would have been allowed to accomplish indirectly what EMTALA would not permit directly.

Background. Martin Cisneros (Cisneros) alleged Drs. Moore and Nixon, and the Emergency Coverage Corp., failed to provide him an appropriate medical screening exam when he went to MNGH’s emergency room (ER) because of pain in

his eye. MNGH had contracted with Emergency Coverage Corp., to provide physicians to staff its ER and treat patients who sought treatment there; however, the contract did not provide for indemnification. The two doctors treated Cisneros and their medical diagnosis and treatment of him were the basis of his EMTALA claim.

EMTALA. If an individual comes to the emergency department of a hospital, EMTALA requires the hospital to provide an appropriate medical screening examination to determine whether an emergency medical condition exists. The examination must be conducted by qualified medical or nursing personnel and if an emergency medical condition is determined to exist, the hospital must provide any necessary stabilizing treatment or an appropriate transfer. If the hospital admits the individual as an inpatient for further treatment, the hospital’s obligation under EMTALA ends. ■

Cisneros v. Metro Nashville General Hospital, M.D. Tenn., March 5, 2013, Health Care Compliance Reporter, ¶801,799

Iowa, Michigan, New Hampshire, and West Virginia receive conditional approval to run state partnership marketplaces

HHS granted four more states conditional approval to operate state partnership health insurance marketplaces as the Patient Protection and Affordable Care Act (PPACA) (111-148) continues to be put into action. Iowa, Michigan, New Hampshire, and West Virginia will have open enrollment available beginning in October 2013. Currently, 24 states and the District of Columbia have conditional approvals from HHS to partially or fully run their marketplaces.

HHS continues to offer states its support to help ensure they have everything they need to establish their marketplaces. HHS' goal is that consumers in every state will be able to buy insurance from qualified health plans directly through the marketplace. In some cases tax credits and cost

sharing assistance will be offered to eligible consumers to help lower their costs. The plans are also intended to guarantee consumers are no longer denied coverage because of a pre-existing condition.

Each state will have a health insurance marketplace, either run by the state, in partnership with HHS, or run entirely by HHS. Some states have created informational websites that discuss what is available for its citizens. There are checklists available for small business and individuals and families who want information regarding how to prepare for when open enrollment begins in October 2013.

CMS Press Release, March 8, 2013

Par Pharmaceuticals settles off-label marketing of Megace® ES for \$45 million

The Department of Justice (DOJ) announced a \$45 million settlement with Par Pharmaceutical Company to resolve allegations Par had engaged in "off-label" marketing of its prescription drug Megace® ES. Par allegedly violated the FDA's drug approval process when it marketed Megace ES for non-AIDS related geriatric wasting, a use that was intended by Par but was never approved by the FDA. A federal magistrate fined Par Pharmaceuticals \$18 million, ordered it to pay \$4.5 million in criminal forfeitures, and \$22.5 million in civil liabilities.

Par pled guilty to a criminal misdemeanor charge for misbranding Megace ES in violation of the Federal Food, Drug and Cosmetic Act (FDCA). Megace ES, a megestrol acetate drug was approved by the FDA to treat anorexia,

cachexia, or other significant weight loss by AIDS patients. Par had criminally misbranded Megace ES because its FDA-approved labeling did not have adequate directions to treat geriatric wasting that was not related to AIDS.

The settlement agreement resolves allegations that Par's off-label marketing caused false claims to be submitted to federal and state health care programs. The settlement resolves three suits filed under the False Claims Act's (31 U.S.C. §3729) whistleblower provisions. Two relators will be awarded \$4.4 million, as part of the government's share of the recovery. Par also agreed to a five-year corporate integrity agreement.

DOJ News, March 5, 2013

Radiologist group and genetic services clinic settle FCA claims

Children's Physician Services of South Texas (CPSST) and Radiology Associates have agreed to settle claims they violated the False Claims Act (FCA) and the Texas Medicaid Fraud Prevention Act. CPSST, a part of the Driscoll Health System, has agreed to pay \$1.5 million, while Radiology Associates, an independent physician group, will pay \$800,000 to settle claims they billed and received double payments for the reading of genetic ultrasounds. From January 1, 2002, to June 1, 2007, Radiology Associates read several thousand ultrasounds for CPSST. The understanding was that CPSST would bill and receive payment for the taking of the ultrasound and Radiology Associates would bill for the reading of the ultrasounds. CPSST is alleged to have billed

for both components without informing Radiology Associates. Upon discovery, Radiology Associates informed CPSST about the double billing, but CPSST allegedly denied billing for the reading component except for a few accidental and isolated occasions. Instead, CPSST is alleged to have directed Radiology Associates to continue to bill for the reading component and reaffirmed that CPSST would only bill for the technical component. Despite additional evidence of double billing, Radiology Associates is alleged to have accepted CPSST's misrepresentations without question and continued to bill for the reading component.

Press Release, U.S. Attorney, S.D. Texas, March 5, 2013

Wolters Kluwer Law & Business connects legal and business communities with timely, specialized expertise and information-enabled solutions to support productivity, accuracy and mobility. Serving customers worldwide, our products include those under the Aspen, Best Case, CCH, ftwilliam, Kluwer Law International, LoislawConnect, MediRegs, and TAGData names.