CCH Health Care Compliance LETTER

Volume 10, Issue 6 health.cch.com March 20, 2007



# Second Illinois hospital denied tax exemption

## by Stacey Fahrner, J.D., M.P.H., Contributing Editor

A second Illinois hospital, The Carle Foundation, has been denied property tax exemption by the state's Department of Revenue for failing to provide a sufficient level of charity care. The Department came to a similar conclusion regarding Provena Covenant Hospital in September, 2006, citing insufficient charity care as the reason for revoking that hospital's property tax exemption. (See *Hospital tax-exemption revoked for insufficient charity care*, *Health Care Compliance Letter*, Vol. 9, Issue 21, Oct. 16, 2006).

According to the Illinois Board of Review (the Board), the Carle Foundation's not-for-profit entities devoted less than one half of one percent of their assets or revenue to charity care, engaged in discriminatory pricing, and used aggressive collection techniques against the uninsured. The Board also noted concern with the close relationship between Carle Hospital, the for-profit Carle Clinic, and the for-profit physician group, Carle Clinic Association.

**Charity care v. community benefit.** These Illinois decisions highlight the ongoing national debate over what constitutes community benefit for tax exemption purposes. According to the Board, a clear distinction needs to be made between charity care and community benefit. Provena reported $14,652,038 of community benefit in 2003; yet the Board found that it had only provided $1.3 million in actual charity care (no-cost or discounted care).

Specifically at issue in the Carle and Provena decisions was the effect of accepting Medicare and Medicaid patients. The hospitals included unreimbursed Medicare and Medicaid costs in their community benefit calculation. Carle stated that the hospital "help[s] relieve the burden on the government and community by providing quality health care at a loss to Medicare and Medicaid patients." Likewise, Provena argued that it provided over $10 million in additional charity care in 2002 by accepting Medicare and Medicaid patients and included unreimbursed costs from those programs in its list of charitable contributions for that year. Illinois courts, however, consistently have rejected the idea that unreimbursed Medicare and Medicaid costs represent charity care. The Board in Carle agreed:

> Entering into a Medicaid contract, or any other payor contract, is not required under the law; hospitals are not compelled to enter into these payor contracts. Voluntarily entering into elective contracts is a willful business decision made by knowledgeable executives who undoubtedly know in advance that various payor contracts have different financial implications. When they sign such contracts, the terms are implicitly accepted as part of the business equation. It is not charity care. It is not a community benefit.

Wolters Kluwer Law & Business

## Tax Exempt (cont.)

**Discriminatory pricing.** In addition to charity care, Illinois requires that tax-exempt hospitals "make an effort to promulgate fair pricing and payment terms to uninsured patients and, in particular, to low-income uninsured patients." In Carle, the Board found that the Hospital charged the uninsured, including the low-income uninsured, higher prices than insured patients for identical services. The Board also objected to Carle's practice of suing low-income uninsured patients to recover for services rendered:

> When one views the extremely low percentage of actual charity care dollars, in the context of this behavior toward the uninsured population of Champaign County, one can only conclude that Carle Hospital is far removed from implementing and practicing policies that would befit an organization that truly has a "charitable purpose."

**Relationship to for-profit entities.** The relationship between Carle Hospital and the Foundation's for-profit entities was central to the denial of property tax exemption. Under Illinois law, a tax-exempt property must actually and exclusively be used for charitable purposes. The Board's opinion stated that the Hospital and the Clinic were separate entities "only on paper" based on "a long-standing pattern of intimate business connections between the Clinic and the Foundation/Hospital." Those business connections included what the Board concluded was the Clinic's domination of the Hospital's medical staff.

Following the Department of Revenue's decision, Carle issued a statement that the organization disagreed with the Board's findings. Carle claims it provided more than $4.9 million in free and discounted care in fiscal year 2006 and nearly $43.7 million in community benefits. According to the statement, "[T]his decision puts the future of other not-for-profit organizations at risk in our community and across the country." ■

*Champaign County Board of Review Notes on Tax Exempt Applications, Feb. 23, 2007; Carle Foundation Release, Feb. 26, 2007.*

## HIPAA

### Hospital not liable for employee's disclosure of PHI

**by Valerie L. Witmer, J.D., Contributing Editor**

A patient could not recover from a hospital on a theory of vicarious liability after a hospital employee divulged the patient's test results to the patient's sister during a casual conversation at a local bar. The Illinois Supreme Court unanimously rejected the patient's claims against the hospital because the employee was acting outside the scope of her employment when she disclosed the patient's confidential information.

While filing test results at the hospital, the employee saw the results of the patient's blood test, which indicated that she was pregnant. On a subsequent weekend night, while with friends at a local bar, the employee revealed the fact of the pregnancy to the patient's sister, who had not previously known of it. The patient's lawsuit followed, raising various privacy claims against the employee and the hospital. The claims against the hospital were based on the theory that the hospital was vicariously liable for the actions of its employee.

**Scope of employment.** The trial court had dismissed the patient's claims against the hospital, but allowed her to proceed individually against the employee. The appellate court reinstated the action, finding a question as to whether the employee's disclosure was motivated, at least in part, by a purpose to serve the interests of the hospital. The Illinois Supreme Court disagreed with the appellate court and affirmed the trial court's judgment in favor of the hospital, finding that the employee's disclosure of the patient's medical information was outside the scope of her employment.

Although the court recognized that the employee had a continuing duty to maintain patient confidentiality, it found that the other two criteria used to determine the liability of an employer for the conduct of its employee were absent from the case. First, citing to the

CCH Health Care Compliance Letter

**Portfolio Managing Editor**
*Pamela K. Carron, J.D., LL.M*

**Coordinating Editors**
*Susan Smith, J.D., M.A.*
*Stacey Fahrner, J.D., M.P.H.*
*Valerie Witmer, J.D.*

**CCH Washington Bureau**
*Paula Cruickshank*
*DOJ, FTC–John Scorza*
*SEC–Peter Feltman*
*Health Law–Catherine Hubbard, M.A.*
*Tax–Jeff Carlson, Steve Cooper*

**Designer**
*Heather Jonas*

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.

*CCH Health Care Compliance Letter* is published 24 times a year by CCH, a Wolters Kluwer business, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is $305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A. 

hospital's Health Insurance Portability and Accountability Act training program, confidentiality policy, and code of conduct, the court determined that the employee's disclosure of the patient's test results was not the kind of conduct she was employed to perform. Second, emphasizing that the disclosure was in direct contravention of the hospital's confidentiality policy, the court found that the employee's conduct was in no way motivated by a purpose to serve the hospital. The court concluded, "[T]he only reasonable inference from the undisputed facts is that [the employee's] motivation was solely and exclusively personal and not related to her position as an employee of [the hospital]." ■

*Bagent v. Blessing Care Corp., Illinois Supreme Court, No. 102430, Jan. 19, 2007, Health Care Compliance Letter, ¶800,281.*

## Fraud and Abuse

### MSP statute a dead end for Brockovich's *qui tam* suits

**by Stacey Fahrner, J.D., M.P.H., Contributing Editor**

"*Qui tam*" suits alleging violations of the Medicare secondary payer (MSP) statute have hit a road block in the federal court system based on lack of constitutional standing. Erin Brockovich, the legal assistant who was the subject of the 2000 movie "Erin Brockovich," has filed over 30 suits alleging that hospitals and health systems have violated the MSP statute by injuring Medicare beneficiaries and improperly billing Medicare for treatment of those injuries.

Under the MSP statute, a Medicare payment "may not be made ... with respect to any item or service to the extent that payment has been made or can reasonably be expected to be made" under a primary plan. According to Brockovich, as health care providers participating in Medicare and carrying their own risk, hospitals must reimburse Medicare for any medical service, treatment, or medication necessary to treat injuries they caused. In response, VanGuard Health System and Scripps Health argued that Brockovich was not an injured Medicare beneficiary and, therefore, lacked constitutional standing to proceed.

**Lack of standing.** In both the Scripps and VanGuard cases, Brockovich claimed standing to sue the hospitals as a representative of the federal government, which allegedly was charged incorrectly for treatment of injuries to Medicare beneficiaries. Brockovich contended that the MSP statute is a *qui tam* statute that allows her to sue to redress the injury suffered by the government.

Both federal district courts disagreed, however, concluding that the MSP statute is not a *qui tam* statute because it does not expressly authorize a private citizen to sue on behalf of the government. To put the decisions in context, both courts cited to the federal False Claims Act (FCA), which expressly states that "[a] person may bring a civil action ... for the person and for the United States Government." (*See* 31 U.S.C. § 3730(b)).

The court in the Scripps case elaborated on that idea, stating that the MSP statute lacks typical characteristics of a *qui tam* statute. First, the MSP statute does not provide a relator's bounty calculated as a portion or percentage of the United States' recovery, whereas the FCA awards the relator between 15 and 30 percent of the United States' recovery. Second, the MSP statute does not automatically allocate any of the recovery to the government. Third, Congress added a private cause of action to the MSP statute during the very same month and year it added a true *qui tam* provision to the FCA, suggesting that Congress unequivocally did not intend to create a *qui tam* cause of action in the MSP statute. Finally, unlike typical *qui tam* statutes, the MSP statute does not require the plaintiff to follow procedural safeguards to ensure the government remains fully apprised of the litigation, has the opportunity to participate, and retains the power to make key decisions over the relator's objections. ■

*Brockovich v. Scripps Health, U.S. District Court for the Southern District of California, No. 06-CV-1569-W, Nov. 11, 2006, Health Care Compliance Reporter, ¶800,273; Brockovich v. VanGuard Health System, U.S. District Court for the Central District of California, No. SA CV 06-0547, Oct. 25, 2006, Health Care Compliance Reporter, ¶800,276.*

On The Front Lines

# Teleradiology: Compliance concerns and solutions, Part I

**by Fay Rozovsky, J.D., M.P.H., and Susan Goodwin, R.N., FACHE, Contributing Editors**

*This two-part article is a condensed version of an in-depth review of teleradiology issues related to compliance, clinical risk, and quality that will be published in three parts in the January/February, March/April, and May/June 2007 issues of the Journal of Health Care Compliance. This version is offered as an overview of what promises to be a burgeoning area in the health care field that merits focused attention.*

Teleradiology is not a futuristic idea. It is well ensconced in contemporary medicine. In a 1999 mail survey of 970 radiology practices, with a response rate of 66 percent, the American College of Radiology (ACR) found that 71 percent of practices with more than one radiologist had teleradiology systems and were using those systems to interpret five percent of their studies, while only 30 percent of solo practices were using teleradiology systems. Of the multi-radiologist practices with teleradiology systems, the uses were varied and indicated that by 1999, teleradiology was well established.[1]

Teleradiology technology is filling a void in contemporary health care, offering the prospect of efficient, quality diagnostic imaging. When done well, it can curtail the waiting time for "critical value" diagnostic tests, thereby increasing the prospect of good treatment outcomes. As seen in the following case study, however, in the rush to embrace teleradiology, a number of compliance-driven factors, including risk management, quality, patient safety considerations, and federal and state requirements, have been overlooked.

## Case study

*Allie Wherton, a 76-year-old retired schoolteacher with a history of transient ischemic attacks, slipped and fell off a stepstool in her kitchen. This was not the first time she had fallen in the last six months. By the time her husband found her, she was groggy, queasy, and somewhat disoriented. She complained of a headache and pain in her right knee. Within 15 minutes of calling 9-1-1, a team of emergency medical technicians arrived at the house and started evaluating Ms Wherton. A decision was made to take her to the regional medical center.*

*At the medical center, the emergency physician decided that a time-critical diagnostic imaging series was in order to rule out a stroke. He put the medical center's certified stroke center team on alert that they may have a new admission. The diagnostic imaging center was closed until 7:30 a.m. A contract was in place for a radiology technician to send images to an "overnight" service based in India. The overseas radiologists were licensed to practice in Maryland. Ms. Wherton, however, was a patient in a medical center located in North Carolina. The radiology technician did a skillful job in taking the required images on the medical center's 64-slice CT scan. She punched in the proper codes and sent the images to the radiology group in India. One hour later, an email came in from the Indian radiology group, saying, "Sorry for delay, transmission problems here. No apparent sign of ischemic brain disorder or hematoma."*

*Based on the radiology report, the emergency physician ruled out a stroke. Because Ms. Wherton had lost consciousness for at least a few minutes, she was admitted for observation. Several hours later, the medical center radiologist performed an over-read of the CT scan. Disturbed by what he found, he called the hospitalist responsible for treating Ms. Wherton. "They missed it overseas. She did have a stroke and there is a small hematoma," he said. The hospitalist sounded exasperated. "So that explains it. She has been going down hill for the last two hours," he said. Although she was evaluated promptly by the certified stroke team, it was too late. Ms. Wherton had suffered irreparable brain damage. She was left with impaired speech, impaired eyesight and right-sided weakness of her arm and leg. Later it was learned that the Indian radiology group did not have equipment compatible with interpreting a 64-slice CT scan.*

While teleradiology is a valuable tool in contemporary health care, it involves risks, obligations, and responsibilities that should be addressed when considering a teleradiology service. This two-part article highlights many of those risks, obligations, and responsibilities and offers strategies for a compliance-based approach to teleradiology. Part one addresses the role of teleradiology in contemporary medicine; describes the two prevailing teleradiology models; identifies key issues implicated by the use of teleradiology technology, including credentialing, state licensure, and patient consent; and suggests methods for dealing with these identified concerns.

## Teleradiology models

In contemporary teleradiology, there are two fundamental models for provision of such services: the "Domestic Model" and the "International Model." Although these models are similar in terms of actual services, their delivery processes are different.

In a hospital-based domestic model, teleradiology services may be provided from a remote location after hours by the same radiologists who are providing the services within the organization during the day. Images are read at home, using Picture Archiving and Communication Systems (PACS) digital imaging technology. In a market-based or state-wide domestic model, teleradiology services also may be provided by radiologists who are located in a large urban hospital and are providing teleradiology services to outlying rural hospitals, clinics, or other organizations in the same state or within a defined market. Another type of domestic teleradiology model crosses state lines. A teleradiology company located in one state provides services to hospitals, ambulatory care centers, and other organizations located in other states.

In the international teleradiology model, services are provided during nighttime hours in American-based health care organizations, from locations where it is daytime, including Australia, Switzerland, Spain, India, and other international locations. International teleradiology services may be delivered in one of three ways: (1) by domestic providers temporarily rotated to a foreign location;[2] (2) by domestic providers permanently based in a foreign location; or (3) by foreign providers.[3] In addition to the conveniences provided by the time differences, using foreign providers offers considerable pricing discounts.[4]

Some international models are inconsistent with both the ACR Standard on Teleradiology and the report of the ACR Task Force on International Teleradiology. The ACR standards and report recommend that physicians who provide the official interpretation of images transmitted by teleradiology (1) maintain licensure as may be required for provision of radiology services at both the transmitting and receiving sites, and (2) be credentialed by and have medical staff privileges at every facility at which imaging services are provided.

Regardless of the model chosen, teleradiology has several advantages, such as cost savings and improved access to the professional services of radiologists.[5] The number and complexity of teleradiology models indicates that this is a service sector with lucrative rewards to successful providers. The prospect of financial reward aside, all of the teleradiology models require careful analysis of the key legal, regulatory compliance, quality, and risk management issues facing this innovative approach to health care delivery.

## Key issues in teleradiology

A review by a team of lawyers, compliance officers, quality officers and risk managers would highlight a host of concerns with respect to teleradiology. Several key issues merit analysis and call for strategies to address the identified concerns. The issues addressed in this article include:

- contracting;
- credentialing;
- patient consent;
- data security and privacy;
- transmission capabilities and diagnostic accuracy;
- medical liability and jurisdictional issues;
- clinical communication;
- documentation practices;
- billing and coding; and
- quality assurance processes and accountabilities.

### Contracting and teleradiology

Central to a discussion of teleradiology services is the need for a well-written contract. The contract is an important tool for controlling the relationship between teleradiology providers and hospitals, ambulatory care centers, radiology groups, and other health care entities. It is a vehicle for controlling expectations and avoiding risk potential.

Health care entities that follow a "zero tolerance" approach to regulatory compliance will want the contract to provide a mechanism for terminating the agreement if the teleradiology provider is excluded from participating in Medicare, Medicaid, or other federally funded programs.

### Credentialing: State licensure, accreditation, and regulatory requirements

One of a hospital's responsibilities when initiating the use of teleradiology services is to ensure that the teleradiologists and other personnel are qualified and competent to perform the planned services. Credentialing practices need to address (1) requirements for a teleradiologist to be properly licensed to practice in the state in which services are provided (*i.e.*, where the patient is located), and (2) accreditation and regulatory requirements for verification of qualifications.

### State licensure

An ACR Task Force report examined issues related to licensure and international teleradiology.[6] Many states are still developing licensure laws to address telemedicine. Both ACR and CMS, in the latest interpretive guidelines for hospital conditions of participation[7] and guidance to state survey agencies,[8] have made clear that practitioners must be licensed both in the location where they reside and in the states where they provide services and practice

teleradiology. Further, the hospital is responsible for verifying this information.

## Joint Commission accreditation

The majority of hospitals in the United States currently are accredited by the Joint Commission. In 2004, the Joint Commission introduced standards addressing telemedicine in the Medical Staff chapter of the accreditation manual for hospitals. The Joint Commission noted that:

> [T]hese standards introduce the concept of credentialing and privileging by proxy. Under special circumstances, the originating site (the site where the patient is located at the time the service is provided) is allowed to accept the credentialing and privileging decisions of the distant site (the site where the practitioner providing the professional service is located). As in all other standards, these standards assume that the hospital is following applicable law and regulation such as appropriate licensure to practice medicine or telemedicine in the states where the originating sites and distant sites are located.

The Joint Commission further stated that "licensed independent practitioners who provide official readings of images, tracings, or specimens through a telemedicine link are credentialed and privileged under the contracted services Standard LD.3.50." The "special circumstances" referred to by the Joint Commission require that the "distant site" (the teleradiology provider's location) be accredited by the Joint Commission. Many teleradiology companies became accredited following the introduction of these standards.

The Joint Commission has stated that the expectation is that a hospital will follow applicable laws and regulations with regard to telemedicine services. The concepts of "credentialing by proxy," or credentialing through options for contracted services, however, are not consistent with, and would lead a hospital to be in violation of, CMS hospital conditions of participation. From a compliance standpoint, this is an issue ripe for close scrutiny by the compliance officer and legal counsel.

## CMS conditions of participation

Medicare hospital conditions of participation require that all care be provided by a practitioner who (1) meets a hospital's medical staff criteria for privileges granted and (2) has been granted privileges by a hospital's governing body.[9] In the "credentialing by proxy" model, credentialing and privileging decisions are made by the teleradiology company and accepted by the hospital on the basis of the teleradiology company being Joint Commission-accredited. The hospital's medical staff is not establishing criteria for privileges, examining the qualifications of the teleradiologist to ensure that criteria for privileges are met, or giving a recommendation to the hospital's governing body regarding the privileges that should be granted, nor is the hospital's governing body making the approval decision. In short, a hospital following the Joint Commission approach may not be in compliance with critical hospital conditions of participation.

## Hospital licensure requirements and court rulings

Similar to CMS requirements, state laws and regulations for the licensure of hospitals typically require a hospital's governing body to make the final decisions regarding approval of medical staff membership and granting clinical privileges. If this is a requirement of the state in which a hospital is located, use of the "credentialing by proxy" model would result in hospital noncompliance, thereby risking state licensure agency action.

## Strategies

There are a number of strategies to consider with respect to teleradiology, licensure, and credentialing. First and foremost, it is important to adhere to state licensure laws for medical practice. Second, it is useful to take into consideration the standards and recommendations of recognized professional organizations, including the American College of Radiology and the American Medical Association. Third, the health care facility should address the apparent conflict between the Joint Commission standards and the hospital conditions of participation. The contract will specify that individual teleradiologists must be licensed in the state in which they are located and also in the state in which the hospital is located. These clinicians must be required to be fully credentialed by the hospital and have clinical privileges approved by the hospital's governing body based on recommendations from the hospital's medical staff.

## Patient consent

A strong argument can be made that patients or surrogate decision-makers should be informed when diagnostic images and patient information are transmitted electronically for purposes of teleradiology. It may be significant to them to know that the person providing the service is located in another state or abroad. A patient's decision to give informed consent for teleradiology services may be influenced by knowing that the teleradiologist's services are contracted through a company and that the teleradiologist did not go through the credentialing process of local care providers. Knowing that the equipment used by the distant radiologist is not as sophisticated as that at the originating site and could lead to misinterpretation is material and significant information. The potential risk of data-hacking during transmission of images also is something a reasonable person may want to know.

## Strategies

In terms of mitigating the risks of consent issues in teleradiology, a good strategy is to inform patients that teleradiology services are used by the hospital, ambulatory care center, or medical group. Another strategy is to offer the patient alternatives, including in nonemergent situations, the option to wait until the resident radiologist is available or to go elsewhere for services.

## Conclusion

Part one of this two-part article provided an overview of the role that teleradiology technology is playing in contemporary health care. It described the two fundamental models, the Domestic Model and the International Model, and identified ten key issues concerning teleradiology. The article discussed contracting, credentialing, and patient consent and offered strategies to deal with each of these concerns. Part two of this article will cover the seven remaining issues: data security and privacy, transmission capabilities and diagnostic accuracy, medical liability and jurisdictional issues, clinical communication, documentation practices, billing and coding, and quality assurance processes and accountabilities.

*Fay Rozovsky is the President of The Rozovsky Group, Inc. and a faculty member in the Department of Legal Medicine at Virginia Commonwealth University Medical College and the Barton Certificate Program in Healthcare Risk Management. She has more than two decades of experience in healthcare risk management. She has published more than 500 articles on subjects in health law, risk management, patient safety, and medical ethics. Ms. Rozovsky is a member of the CCH Health Care Compliance Editorial Advisory Board.*

*Susan T. Goodwin is an Assistant Vice President in the Quality, Safety, and Performance Improvement Department of the Hospital Corporation of America, with expertise in the areas of governance/leadership, medical staff affairs, performance improvement, risk management, and regulatory/accreditation compliance. Ms. Goodwin is a registered nurse (RN), a Licensed Risk Manager in Florida, a Certified Professional in Healthcare Quality (CPHQ), a Fellow of the National Association for Healthcare Quality (FNAHQ) and a Fellow of the American College of Healthcare Executives (FACHE). She is currently a member of the Joint Commission's Committee on Healthcare Safety, and the Hospital Professional Technical Advisory Committee (PTAC) representing the National Association for Healthcare Quality (NAHQ).*

1 David B. Larson, Yasmin S. Cypel, Howard Forman, & Jonathan H. Sunshine, *A Comprehensive Portrait of Teleradiology in Radiology Practices: Results from the American College of Radiology's 1999 Survey*, 185 AM. J. ROENTGENOLOGY 24 (2005).

2 Ari Van Moore, et al., *Report of the ACR Task Force on International Teleradiology*, 2 J. AM. C. RADIOLOGY 121-25 (Feb. 2005).

3 Thomas R. McLean & Edward Prichards, *Teleradiology: A case study of the economic and legal considerations in international trade in telemedicine*, HEALTH AFFAIRS, Sept./Oct. 2006, at 1378–85.

4 *Id.*

5 Hematram Yadav, MBBS, MPH, MBA & Wong Yut Lin, DrPH, MPhil, *Patient Confidentiality, Ethics and Licensing in Telemedicine*, 13 ASIA-PAC. J. PUB. HEALTH 36-38 (Supp. 2001).

6 Van Moore, *supra* note 2.

7 CMS, *Survey Protocol, Regulations and Interpretive Guidelines for Hospitals*, State Operations Manual, App. A, §§482.11(c), 482.26(c)(1) (Rev. May 21, 2004).

8 Letter to the State Survey Agency Directors, *CMS Requirements for Hospital Medical Staff Privileging*, S&C-05-04, Nov. 12, 2004.

9 42 C.F.R. §§482.12(a)(5), 482.22(a)(2), 482.22(c)(6).

## Trends

### Panel approves ban on exclusion payment settlements

**by John Scorza, Contributing Editor**

The Senate Judiciary Committee passed a bill to prohibit brand-name drug companies from compensating generic drug companies to delay the entry of generic drugs into the market — a practice known as an exclusion payment settlement. The committee passed the Preserve Access to Affordable Generics Act (S. 316) on February 15, 2007, clearing the bill for consideration by the full Senate.

The bill's supporters say it would lead to more robust competition by generics and could save consumers billions of dollars. Sen. Herb Kohl (D-Wis.), the bill's sponsor, commented, "I believe today's vote shows that many of my colleagues agree that these settlements are anticompetitive and that brand and generic drugs are abusing this practice. Our solution is very simple: Make these anti-consumer patent settlements illegal."

The Federal Trade Commission (FTC) supports the bill. FTC Commissioner Jon Leibowitz told the Judiciary Committee in January that exclusion payment settlements "restrict competition at the expense of consumers, whose access to lower priced generic drugs is delayed, sometimes for years." Leibowitz said these settlements are on the rise as the result of two 2005 appellate court decisions that took a lenient view of them.

A recent FTC study documented the increase. It found that half of the 28 final patent settlements entered into in 2006 between brand-name drug manufacturers and their potential generic drug competitors involved compensation to the generic drug manufacturers and agreements from the generic firms to delay the launch of their equivalent products. By comparison, none of the 14 drug patent settlements entered into in 2004 contained those provisions.

The pharmaceutical industry opposes the bill and contends that strong patents are necessary to allow pharmaceutical companies to recoup their investments. The drug companies also warn that blanket prohibitions on certain types of settlements could lead to extended patent litigation. ■

*CCH Washington Bureau, Feb. 16, 2007.*

# In the News

## IG identifies vulnerabilities in Medicare program

Daniel R. Levinson, HHS Inspector General, identified three areas of vulnerabilities related to the Medicare program in his testimony before the U.S. House of Representatives Ways and Means Subcommittee on Health and Oversight on March 8, 2007. According to Levinson, those areas are: (1) integrity of Medicare payments; (2) quality of care in nursing facilities; and (3) Medicare Part D. Within the broad category of Medicare payments, he identified more specific vulnerabilities within certain services and provider types, including medical equipment and supplies, home health agencies, hospital payments and operations, and Part B prescription drugs. He also discussed some of the Office of Inspector General's (OIG's) ongoing work that addresses these vulnerabilities and took a prospective look at future challenges. According to Levinson, OIG remains "committed to proactively identifying program weaknesses and vulnerabilities to help prevent fraud, waste, and abuse and to improve quality of care."

*OIG Testimony, Mar. 8, 2007, Health Care Compliance Reporter, ¶530,521.*

## CMS extends Medicare payment project

The Centers for Medicare and Medicaid Services (CMS) has approved a three-year extension of the Premier Hospital Quality Incentive Demonstration (PHQID). The recently released second-year results of the demonstration show substantial improvement in quality of care across five clinical focus areas, with total gains over the first two years of 11.8 percent. CMS will use the three-year extension to test new incentive models and develop new ways to measure quality. During PHQID's first three years, only top-performing hospitals were eligible to receive incentive payments. The three-year extension will test the effectiveness of offering incentive payments to hospitals achieving a defined level of quality, and to hospitals achieving the greatest improvement in quality that also achieve the quality threshold. The extension will continue to track hospital performance in the five identified clinical focus areas, with flexibility to add quality measures and clinical conditions in the fifth and sixth years.

*HFMA News Release, Feb. 27, 2007.*

## Prescription Project targets conflicts of interest in pharmaceutical marketing

The Prescription Project called on academic medical centers, professional medical societies, and public and private payers to end conflicts of interest resulting from the $12 billion spent annually on pharmaceutical marketing. The Prescription Project is an initiative of Community Catalyst, a Boston-based health care advocacy organization, in partnership with the Institute on Medicine as a Profession. Funded by a $6 million grant from The Pew Charitable Trusts, the Project will work over the next two years with medical and consumer stakeholders, policy makers, and public and private payers to conduct and publish research on conflicts of interest, advocate for policy reforms that will eliminate such conflicts, and promote prescription practices that are based on scientific evidence. The Prescription Project is the first comprehensive campaign aimed at ending conflicts of interest at academic medical centers, in professional medical societies, and among public and private payers.