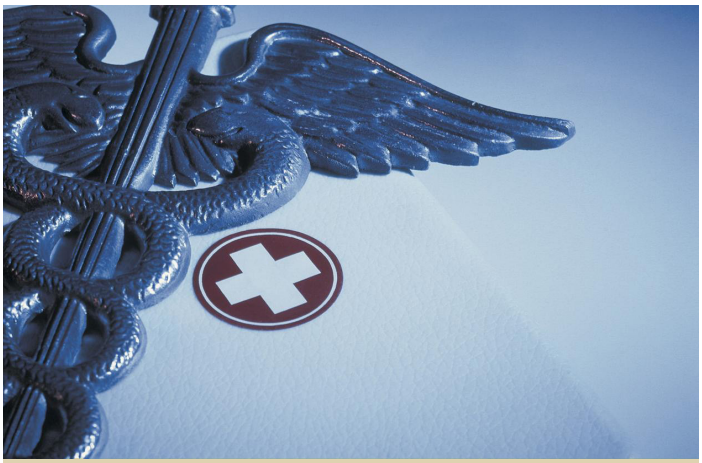

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# HEALTHCARE **LEGAL**NEWS

## DO SUBSIDIZED HEALTH CARE PLANS PURCHASED UNDER THE AFFORDABLE CARE ACT TRIGGER THE ANTI-KICKBACK STATUTE?

*by Scott F. Roberts, who is Of Counsel in Dickinson Wright's Troy office, and can be reached at 248.433.7211 or sroberts@dickinsonwright.com*

The advent of federally subsidized private pay health insurance under the Affordable Care Act has the potential to expand the application of the federal anti-kickback statute beyond just Medicare, Medicaid, and Tricare. The Affordable Care Act (sometimes referred to as "Obamacare") currently allows individuals to purchase and receive private health insurance coverage from state or federal health insurance exchanges. While not all individuals are eligible for subsidies, a substantial number of people will receive income-based federal subsidies that have the potential to trigger the federal anti-kickback statute, and by extension, the False Claims Act.

The federal anti-kickback statute applies to referrals involving a "Federal health care program," which is defined as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government." On October 30, the Secretary of Health and Human Services announced in a letter to a member of Congress that under HHS's interpretation of the anti-kickback statute, Qualified Health Plans subsidized under the Affordable Care Act would not be considered to be a part of a "federal health program". The letter states that HHS's position was based on "careful review" of the definition of a "Federal health care program" and was made "in consultation with the Department of Justice." It would therefore appear that HHS is taking the position that the federal government is not directly funding health insurance benefits but is instead providing indirect financial support to purchasers in the form of tax subsidies and premium assistance.[1] However, this rationale would likely not apply to "reduced cost sharing subsidies" that provide lower premiums and co-pays to low income individuals because such subsidies are paid directly to the insurance plans.

There are many reasons to take HHS's October 30th letter with a grain of salt. First, this was not formal guidance issued by the HHS, but instead came in the form of a non-binding letter, meaning HHS could very well change its interpretation with little to no warning. Courts would not be bound by this type of informal guidance, meaning a federally subsidized Qualified Health Plan could still be the basis for a whistleblower's Qui Tam lawsuit based on an anti-kickback claim. Moreover, HHS's interpretation does not appear to be on particularly strong legal footing with respect to "reduced cost sharing subsidies," and the precise legal analysis was never explained in the letter.

Nonetheless, there is likely not an immediate need to ensure that practitioners who accept Qualified Health Plans, but do not accept Medicare, Medicaid, and Tricare comply with the federal anti-kickback statute. However, given the lack of legal analysis contained in the October 30, 2013 letter, it is likely that HHS's position will be readdressed, and possibly even reversed, in future guidance documents.

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1 HHS has yet to publically explain its legal reasoning for not applying the anti-kickback statute to the ACA. However, many commenters believe the actual rationale is based on policy, as opposed to legal, reasons. Some commenters have speculated that the decision was made in order to allow pharmaceutical companies to provide co-payment assistance to those who could not afford to purchase pricey prescription drugs. Such payments would be considered illegal "kickbacks" under the anti-kickback statute. Still others have speculated that the rationale behind the October 30, 2013 letter is that HHS feared that application of the act to Qualified Health Plans would confuse certain providers, which could in turn interfere with, or at the very least distract from, the 2014 ACA rollout. This confusion could result from the fact that providers may not be able to readily distinguish between subsidized and non-subsidized health insurance policies.

## LEGISLATION PERMITTING HEALTHCARE PROVIDERS TO NEGOTIATE JOINTLY WITH HEALTH INSURERS INTRODUCED IN CONGRESS

*by James M. Burns, who is a Member in Dickinson Wright's Washington, DC office, and can be reached at 202.659.6945 or jmburns@dickinsonwright.com*

Legislation was recently introduced by Representative John Conyers (D-Michigan) that would permit healthcare providers to negotiate jointly with health insurers concerning contract terms without running afoul of the antitrust laws. The bill, the "Quality Health Care Coalition Act of 2014," (H.R. 4077), has been referred to the House Judiciary's Subcommittee on Regulatory Reform, Commercial and Antitrust Law for further action.

> In introducing the legislation, Representative Conyers stated that:
>
> [O]ver the last several decades, the health insurance market has become exceedingly concentrated, dominated by a few large insurers offering a limited number of health insurance plans. This has occurred in large part because of insurers' immunity from federal antitrust laws. In contrast, our nation's physicians and health care providers are afforded no comparable protections. This unbalanced playing field ultimately means consumers lose out with higher healthcare costs and poorer care. H.R. 4077 allows for physicians to negotiate with insurers on a level playing field, ensuring heightened quality standards for patient care.

Notably, Representative Conyers has introduced similar legislation in the past, without success. However, the legislation enjoys a degree of bipartisan support this Congress, with Republicans in both the House and Senate having also introduced legislation containing provisions similar to those in Representative Conyers's bill. Specifically, H.R. 2300, which was introduced by Representative Tom Price (R. Georgia) last June, would permit healthcare providers to negotiate jointly with insurers, as does S. 1851, which was introduced by Senator John McCain (R. Arizona) last December. However, both H.R. 2300 and S. 1851 are much larger bills that also seek to repeal the Affordable Care Act, and thus those bills are unlikely to garner support in the House or Senate from Democratic lawmakers.

Nonetheless, the fact that these Republican-sponsored bills contain language that is virtually identical to that in Representative Conyers's bill suggests that the prospects for H.R. 4077 are probably brighter this year than they have been at any time since 2000, when similar legislation was passed in the House but stalled in the Senate. Will Representative Conyers's legislation finally "cross the finish line" this Congress? Time will tell; stay tuned.

## PEER REVIEW IS NOT ALWAYS PRIVILEGED

*by Keith C. Dennen, who is a Member in Dickinson Wright's Nashville office, and can be reached at 615.780.1106 or kdennen@dickinsonwrwright.com*

Hospitals, ambulatory surgery centers and independent diagnostic centers cannot exist without physicians and other medical providers. In order to practice at those facilities, the medical professional often is required to be "admitted" to the medical staff of the facility. Although admission to the medical staff provides privileges, it often requires that the professional agree to a periodic competency review by other members of the medical staff – i.e. a peer review.

In theory, peer review is the best manner for evaluating a practitioner's competency. Presumably, other practitioners in the same location possess an understanding of all of the factors that determine whether a person is professionally competent. In practice, because of professional jealousy, envy or simple competition, peer review has been used to "punish" practitioners who are too successful, too aggressive or who simply do not observe the unspoken rules of the professional hierarchy. In the past, a practitioner who was treated unfairly in a peer review process often would resign from the hospital and relocate. The advent of the National Practitioner Databank requiring the reporting of every negative peer review event makes relocation untenable.

The laws of all states and the District of Columbia provide that "peer review proceedings" are "privileged." Therefore, a practitioner who contends that he or she has been injured by an unfair peer review proceeding is unable to discover what was said or done in the peer review hearing. In many instances, the practitioner is unable to determine what materials the peer review committee reviewed to make its decision.

Although the Health Care Quality Improvement Act, 28 U.S.C. §§ 11101 – 11152, grants immunity to participants in a peer review, HCQIA does not make peer review proceedings privileged. Likewise, as noted recently in *Roberts v. Legacy Meridian Park Hospital, Inc., No. 3:13-cv-01136-SI (D. Ore. Apr. 25, 2014)*, federal courts do not recognize a "common law" privilege for peer review proceedings. Therefore, in cases in which violations of federal statutes are alleged (e.g., discrimination, antitrust), the federal courts will allow the physician

to obtain discovery concerning the peer review process, including information about peer review proceedings concerning other similarly situated physicians. Consistent with this finding, the federal district court in the *Roberts* case allowed discovery of the plaintiffs' peer review records as well as the peer review records of other hospital physicians in the same specialty.

For practitioners who are subject to adverse peer review, the lack of a federal peer review privilege makes federal court the best venue for any proceeding. For practitioners who are reviewers in peer review proceedings, the lack of a federal peer review privilege means that great caution should be exercised to ensure that the peer review proceeding is free of bias, prejudice or other impropriety. The record should reflect all materials considered and the basis for any adverse action.

## HIPAA VIOLATION RESULTS IN $4.8 MILLION SETTLEMENT

*by Rose J. Willis, who is a Member in Dickinson Wright's Troy office, and can be reached at 248.433.7584 or rwillis@dickinsonwright.com*

While most healthcare providers know to pay close attention to the HIPAA rules when setting up their information technology systems, recent events have demonstrated that this close scrutiny should also be applied to computer reconfigurations and other IT system changes. According to the Department of Health and Human Services Office for Civil Rights ("OCR"), a "reconfiguration" of a computer server involving two healthcare providers caused the health information of 6,800 patients to be disclosed to Internet search engines. The healthcare providers, New York-Presbyterian Hospital and Columbia University Medical Center, each entered into a settlement and a Corrective Action Plan with OCR requiring payment of $4.8 million to OCR.

According to OCR, the hospitals failed to conduct an accurate and thorough risk analysis that incorporates all information technology ("IT") equipment, applications, and data systems utilizing electronic protected health information ("ePHI"). Additionally, they failed to implement processes for assessing and monitoring all IT equipment, applications, and data systems that were linked to their patient databases prior to the breach incident, and failed to implement security measures sufficient to reduce the risks and vulnerabilities to its ePHI to a reasonable and appropriate level. The hospitals also failed to implement appropriate policies and procedures for authorizing access to their patient databases, and they failed to comply with their HIPAA security policies on information access management.

Under the HIPAA Security Rule, most healthcare providers are required to conduct a risk analysis of, among other things, their IT equipment. Healthcare providers are also required to implement HIPAA security policies and procedures to reduce their risk of a potential HIPAA violation and vulnerabilities in their IT systems. Whenever a change is made to a healthcare provider's IT systems, a new risk analysis should be conducted to identify any potential risk of improper disclosure of ePHI as a result of the change. Any such risk must be eliminated or sufficiently reduced prior to implementing the change to avoid a violation of HIPAA and the costly penalties that go along with it.

## HHS HEAT INITIATIVE CONTINUES FRAUD CRACKDOWN

*by Scott Roberts*

A number of recent cases demonstrate Health and Human Services' ("HHS") Health Care Fraud Prevention and Enforcement Action Team's ("HEAT") continued success in cracking down on healthcare provider fraud. Since 2009, the federal government has recovered more than $12 Billion dollars under the False Claims Act from cases involving health care programs. Through the HEAT initiative, HHS has brought a number of False Claims Act cases against hospitals and physician groups resulting in several large settlements and verdicts. These cases typically arise in one of three ways: (1) the physician group or hospital self-reports the problem, (2) violations are discovered in the course of an investigation into another matter or entity, or (3) a person or entity brings a "qui tam" whistleblower suit against the group or hospital.

Typically, physician groups that self-report a violation receive more favorable treatment than those groups that wait until a whistleblower or other investigation brings the violation to light. This was seen in a recent settlement involving a Montana hospital that provided improper financial incentives to individual physicians and physician groups. The incentives were discovered by an internal audit conducted by the hospital, which then reported the violation to the government. The hospital and government settled the matter for $3.85 million.

Situations might also arise where the government discovers certain improprieties when investigating other entities or potential legal violations. One example of this would be a recent Ohio case involving a cardiologist and a medical corporation run by the cardiologist. In that case, the government was investigating a hospital for alleged violations of the Stark Law when it discovered that the cardiologist group caused the hospital to submit fraudulent claims to Medicare. The case was settled for $1 million before it could be brought to trial.

Physician groups and hospitals that wait until a whistleblower suit is brought will often receive the harshest penalties and judgments. This was seen in the Tuomey Healthcare case, which involved a hospital entering into a number of contracts with local physicians that provided financial incentives for physicians referring patients to the hospital. One of the outside physicians eventually blew the whistle on the scheme and brought a qui tam suit against the hospital under the False Claims Act. The hospital took the case to trial, where it eventually received a verdict against it for $237 million. Another recent example would be the Health Dimension Rehabilitation case, where a rival company brought a whistleblower action against a national physical therapy company for paying local companies for Medicare referrals. In that case, the physical therapy company settled the matter after the U.S. D.O.J. took over the case for approximately $30 million.

## TENNESSEE ATTORNEY GENERAL STATES THAT PHYSICAL THERAPISTS CANNOT PERFORM TRIGGER-POINT DRY NEEDLING

*by Keith Dennen*

In an opinion released on June 19, 2014, the Office of the Tennessee Attorney General stated that Physical Therapists cannot lawfully

perform Intramuscular Manual Therapy or Trigger-Point Dry Needling. Dry Needling therapy involves application of a fine, filiform needles to the neuromusculoskeletal system to restore movement, reduce pain and address other musculoskeletal disorders. That practice, the Attorney General found, was similar to acupuncture – a separate branch of medicine.

To support its opinion, the Attorney General noted:

- The Tennessee Occupational and Physical Therapy Practice Act, does not specifically authorize the invasive use of needles for therapeutic purposes.
- Dry Needling and acupuncture are similar therapies, and physical therapists may not perform acupuncture pursuant to Tennessee Code Annotated section 63-6-1002(a) – (b).
- The Rules of the Tennessee Board of Physical Therapy allow physical therapists to perform kinesiologic electromyography and diagnostic electromyography for diagnostic or academic purposes and then only in a university setting or upon referral from an allopathic or osteopathic physician, dentist or podiatrist.

The opinions of the Office of Attorney General are not binding upon a court of law; however, they are given precedential effect. The Attorney General suggested that the appropriate manner of addressing the issue would be by legislative amendment. Until an amendment is enacted, physical therapists and practitioners who employ physical therapists should not submit claims for Dry Needling therapy to Medicare or Medicaid as those claims could be deemed "fraudulent." For more information, see Tennessee Attorney General Opinion No. 14-62 (June 19, 2014).

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