

## Judicial guidance on peer review

by *Connie Alt*

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**Peer review** means, very simply, “evaluation of professional services rendered by a person licensed to practice a profession.” Iowa Code §147.1(4). It applies not only to doctors, but to nurses, and other allied health professionals.

**Peer review records** are defined very broadly in the Iowa Code, to include: all complaint files, investigation files, reports or other investigative information relating to discipline or professional competence in the possession of a peer review committee. Iowa Code §147.135(2).

A **Peer Review Committee** is also broadly defined as “one or more persons acting in a peer review capacity” who are members of the staff, professional society, or group medical practice with a formal peer review process. Iowa Code §147.1(5).

Iowa law provides that peer review records are protected as confidential and privileged and are not subject to discovery or subpoena and are not admissible at trial or hearing. This protection is based upon an “overwhelming public interest” in fostering the continued improvement in the care and treatment of patients including candid evaluations of clinical practices with constructive criticism.

Recently the Iowa Court of Appeals, in *Orgovanyi v Henry County, et al.*, held that based upon the record in that case, the peer review privilege did not protect a “patient safety report” from discovery. The ruling is concerning, but does give us some direction as to how to modify documentation and procedures so that such documents would more likely be protected.

The Court made a distinction between loss prevention (not protected) and peer review (protected), and held that information must be in the possession of the peer review committee – whether or not generated by the committee – to constitute peer review and gain the statutory protection.

In *Orgovanyi*, the risk manager had possession of the patient safety report and testified that she would typically analyze these reports and provide summary information to the MEC (peer review). She did not testify that she had provided the report to a peer review committee and did not testify that she was an agent of the peer review committee. Based on this record, the Court found that there was insufficient evidence that the report was “in the possession of a peer review committee or an employee of a peer review committee.” The

Court stated that absent other information to the contrary, it was “logical” that the patient safety report was not part of the peer review process but part of the hospital’s “regular risk management system.”

What does this case mean to you? While your institution may approach these types of reports in such a way that you are already protected, hospitals (and clinics) should re-evaluate their quality reporting systems to be sure that you have procedures in place that give you the best chance that all such reports which contain critiques of professionals are protected under the peer review statute.

If your hospital or clinic solicits reports – whether they are called Patient Safety Reports, Variance Reports, Quality Reports, or Incident Reports, the following checklist may be helpful:

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1. Are reports directed to someone who has been designated as an agent of the peer review committee?
2. Does the person receiving these reports understand that they are the beginning of the peer review process as it relates to such reports, and understand that they are tasked to:
  - Evaluate all reports as an agent of the peer review committee; and
  - Send those reports that are related to a health care providers' professional care or competence to a peer review committee for review and action as the peer review committee sees fit.
3. To the extent any such reports are in the hands of the initial reviewer, does he or she understand that possession is only as an agent of the peer review committee?
4. Does the peer review committee receive and review these reports? (Remember that PRC is a broad term and need not be the same for all purposes).
5. Have you modified existing policies to be sure that they accurately define the above roles and procedures?
6. Have you educated your staff about the broad reach of peer review protections, the meaning of peer review and the requirements to obtain and maintain protection of these documents?

This checklist does not guarantee protection of such documentation from discovery in litigation, but modifications to your policies and practices will go a long way to support the argument that protection exists.

Remember there may be more than one way to accomplish effective peer review that provides protection. Feel free to call us to see if your approach has what it needs to protect the documents. If you have any questions or need further assistance please contact Connie Alt or any member of the Health Law Section. ■

## Fraud and abuse and health reform

by Diane Kutzko [dhk@shuttleworthlaw.com](mailto:dhk@shuttleworthlaw.com)

In addition to wide ranging insurance reforms and changes concerning the delivery of health care, the Patient Protection and Affordable Care Act (PPACA) contained a number of significant fraud and abuse provisions. This article provides a brief overview of some of these; subsequent newsletters and client alerts will continue to highlight developments and enforcement in this area.

By way of background, CMS defines fraud as intentional misrepresentations that an individual knows to be false or does not believe to be true. Abuse is defined by CMS as practices that although not normally considered fraudulent are inconsistent with accepted sound medical, business, or fiscal practices. The practices may, directly or indirectly, result in unnecessary costs, improper payment, or payment for services that fail to meet professionally recognized standards of care, or which are medically unnecessary. It is predicted that providers will face increased fraud and abuse enforcement under PPACA – there is a first year allocation of \$95 million to fraud enforcement, with a total of \$250 million over the first five years.

### 1. Sixty day overpayment return

PPACA contained a “report and return” requirement for overpayments to Medicare. Under the new law, providers are legally obligated to report and return overpayments within sixty days of discovering overpayment. This requirement was effective immediately upon enactment (March of 2010). The sixty day period begins when the knowledge of the overpayment is obtained. A failure to report and return is an automatic violation of the federal False Claims Act.

The issue of how to go about reporting overpayments and repaying is fact specific and depends in part on the payer and the amount of overpayment. Care should be taken in determining whether there has been an overpayment and how to handle and legal counsel should be consulted for guidance.

### 2. Payment suspension

PPACA gives the Department of Health and Human Services (HHS) new powers to withhold payments to a provider where there is a “credible allegation” of fraud and requires the Department to issue regulations

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defining what constitutes such a “credible allegation.” This power is significant because many providers are dependent on the income stream from Medicare; there is a risk that suspension pending resolution of an investigation could force a provider out of business.

### **3. Disclosure Requirements to Patients re Physician Ownership Interest in Certain Imaging Services**

In recent years, many physicians have expanded their practices to provide diagnostic imaging and other “ancillary services” to their patients under the “in office ancillary service” exception to the Stark law’s prohibition against physician referral of patients to entities in which they have a financial interest. Effective January 1, 2011, physician group practices who provide MRI, CT, and PET services payable by Medicare pursuant to that Stark exception are required to make certain disclosures to patients concerning these services. This change reflects the government’s concerns about the rapid growth of ancillary services. The notice to patients must include a list of five alternative providers of such services within a 25 mile radius (excluding hospitals). The notice must be in writing and must be provided each time the patient is referred for such services. Notably, there is no exception for emergency or time sensitive tests.

This requirement does *not* apply to hospitals providing imaging services.

### **4. Self Reporting Protocols Under the Stark Law**

On September 23, 2010, CMS released a Voluntary Self-Referral Disclosure Protocol pursuant to PPACA’s requirement that it do so. Under this Protocol, providers who discover that they have violated the Stark law’s prohibitions against self-referrals to report such violations within the later of two dates: 60 days after the date the overpayment was identified; or the date any corresponding cost report is due.

Although the protocol is controversial, this is a significant development because Stark violations bear with them significant penalties, regardless of a

provider’s lack of intent to violate the statute. Self disclosure may – but is not guaranteed to – result in the reduction of statutory penalties.

The scope of what constitutes a violation of the Stark law and the pros and cons to voluntary disclosure are beyond the scope of this article. But if some violation is identified, it is critical that you consult with legal counsel to determine how to proceed.

### **5. Mandatory compliance programs**

Under PPACA, the implementation of a compliance program will become a condition of enrollment in Medicare and Medicaid. The time frame for implementation for Medicare or Medicaid skilled nursing facilities (SNFs) is March 2013; and HHS is required to announce the required core elements by March 2012. For other providers, there is no set timeline as of now. However, it is anticipated that when regulations come out for both SNFs and other providers, the compliance programs will look much like the model programs in earlier Office of Inspector General (OIG) guidances.

Many of you implemented compliance programs in the 1990s in response to an earlier wave of Medicare and Medicaid enforcement, as the existence of a compliance program formed a basis for reduced penalties in the event of violations of federal billing and other regulations. These programs should be reviewed. If they have fallen into disuse, they should be updated and revived. For those entities that do not have a compliance program, it is advisable in light of heightened enforcement to consider implementing a formal plan at the present time using previous Office of Inspector General guidances, with the understanding that the program may need to be updated when the regulations are promulgated. The program can be tailored to the size and scope of a particular practice.

For questions or assistance, contact your Shuttleworth & Ingersoll attorney or Diane Kutzko at [dhk@shuttleworthlaw.com](mailto:dhk@shuttleworthlaw.com). ■

*With health reform comes heightened fraud and abuse enforcement.*

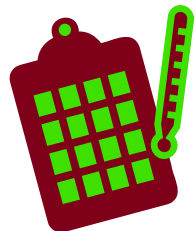
# Case law update

by Nancy Penner

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In addition to the new case on peer review records discussed in this issue, there are several other recent Iowa cases of interest.

## Confirmation of a strong right to privacy in medical records



In a December 30, 2010 opinion, the Iowa Supreme Court reaffirmed that individuals have a strong statutory and constitutional right to privacy in their medical records. The issue originally presented in *Ashenfelter v. Mulligan*, 2010 Iowa Sup. LEXIS 145 (Iowa 2010), was whether grandparents had the right to their own adult daughter's medical and mental health records in a grandparent visitation case. The district court said "yes;" the Iowa Supreme Court said "no."

While the case was considered "moot" because the Iowa legislature since limited a grandparent's right to visitation, the Court went on to discuss the medical record disclosure because "individual privacy interest in medical and mental health records presents an issue of great public interest" and the issue might arise again.

The Court provided a helpful historical summary of Iowa law as to medical record disclosure issues. The Court essentially reinforced and confirmed prior Iowa law and clarified a few areas as well:

- First, the Court held that medical records (even though they are not actually "testimony") are indeed

protected by Iowa's statute that prohibits a health care provider from disclosing patient confidences in giving testimony.

- Second, the Court reaffirmed that essentially only the patient him or herself can waive the privacy of their records by placing their medical condition at issue in a lawsuit. (In other words, the grandparents could not get around the privacy of the records by arguing *they* needed the records for their claim).
- Third, the Court reaffirmed there is a constitutional right to privacy in medical and mental health records.
- Finally, the Court raised a new question in Iowa as to whether the constitutional right to privacy could *ever* be defeated by balancing the other side's need for medical records in a civil case. The Court recognized that the public's interest may outweigh the individual's interest in some cases (i.e. in criminal cases), but noted that the U.S. Supreme Court has suggested that a balancing test may "never be appropriate in a civil case." The Court in *Ashenfelter* did not decide this issue.

In summary, the Court held that the grandparent's "desire for visitation cannot overcome [their adult daughter's] constitutional and statutory privilege against production of her medical and mental health records."

The case does not change the rules that providers use in determining when to disclose records (i.e. generally disclosure is pursuant to a proper authorization signed by the patient or legal

representative). However, the case provides new authority for lawyers who are attempting to either seek or protect medical records. So, as always, when there is any doubt or question about disclosure of records and whether it is permissible under the specific situation presented to you, contact your legal counsel for assistance.

## Parental releases offer less protection to the sponsors of activities for kids.

On September 5, 2010 the Iowa Supreme Court issued a case making "new law" on the enforceability of



parental releases. *Galloway v. Iowa*, 790 N.W.2d 252 (Iowa 2010), involved a release that a mother signed for her 14 year old daughter to participate in an Upward Bound trip. The daughter was hit by a car on the trip. They sued. The Iowa Supreme Court held that "preinjury releases executed by parents purporting to waive the personal injury claims of their minor children violate public policy grounds and are therefore unenforceable."

The Court discussed several public policy reasons for its decision and noted that the majority of states deciding this issue have also found such releases unenforceable. The Court discussed the fact that parents are unable to settle a claim on behalf of their minor children without court approval *after* an injury has occurred. This supports the limitation of parental authority

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to make decisions for their children before an injury occurs. The Court also discussed that a child is less able than an adult to protect him or herself during activities but it is the adult who executes the waiver.

While the Court held that releases are unenforceable, there are reasons to continue the practice of having parents sign such releases.

First, the legislature could address this issue, as recognized by the *Galloway* Court. Further, each case is different and the facts of a given case may result in a release being enforceable. For example, the participation of a parent in the activity could distinguish a future case from the *Galloway* case and result in a different outcome. In

addition, the release can be drafted in such a way as to release any claim a parent might be able to bring on their own behalf which the *Galloway* case does not preclude. A signed parental release also provides some basic documentation that the parent is aware of the activity and agrees to the child's participation. ■

## Health care reform update: Is the statute constitutional?

by Ryan Prahm [rjp@shuttleworthlaw.com](mailto:rjp@shuttleworthlaw.com)

Recent challenges to the Patient Protection and Affordable Care Act (the "Health Care Reform Act" or "Act"), raise the issue of the constitutionality of the Act, focusing mainly on the "minimum essential coverage provision" more commonly known as the individual mandate (Section 1501 of the Act). The individual mandate imposes a penalty that is applied on the tax return of those who do not purchase adequate health insurance coverage. Four cases that have challenged this provision, as well as the Act itself, are discussed below.

### Legal Backdrop

Each case addressed below raises the question of whether Congress has the authority under the Commerce Clause and the General Welfare Clause of the Constitution to require every individual to purchase health insurance and every employer with 50 or more employees to offer health insurance to its employees or be subject to a penalty. United States Supreme Court precedent has established that Congress has the ability to regulate economic activities, that, when taken in the aggregate, substantially affect interstate commerce. Further, the Supreme Court has recognized Congress's power to regulate wholly intrastate non-economic activities that form a critical part of a larger regulation of economic activity, in which the entire regulatory scheme could be undercut unless the intrastate activity was regulated.

Unquestionably, individuals that purchase health insurance are participating in an economic activity that in the aggregate has a substantial effect on interstate commerce. Thus, an act by Congress regulating the purchase of health insurance would be a constitutional exercise of Congress' powers. However, in a broad

sense, the question in these cases boils down to whether an individual, who chooses not to purchase health care insurance, is participating in an "economic activity." Those challenging the individual mandate have drawn a distinction between being involved in an "economic activity" and making a decision to be "inactive" by not participating in the "economic activity" of purchasing health insurance. Proponents of the Act counter that the decision not to buy insurance is an action in itself. Though it may appear to be a matter of semantics in the colloquial sense, it will be semantics that dictate whether the individual mandate, and possibly the Act, will survive.

### Eastern District of Michigan and Western District of Virginia – Constitutional

In *Thomas More Law Center, et al v. Barack Hussein Obama, et al*, No. 10-CV-11156, 2010 U.S. Dist. LEXIS 107416, \*1 (E.D.S.D. Mich. Oct. 7, 2010), the Honorable Judge Steeh denied a motion for a preliminary injunction, and decided as a matter of law that the challenge to the individual mandate provision found in the Act had failed on its merits. The plaintiff (a national public interest law firm in Ann Arbor, MI) contended that the individual mandate was unconstitutional use of Congressional power via the Commerce Clause. The court found that the individual mandate is of the type of Congressional regulation supported by Supreme Court precedent because: (1) the Act regulates economic activity (i.e. - how to pay for health care services, which has a direct and substantial impact on the interstate health care market); and (2) the minimum coverage provision is essential to the Act's larger regulation of the interstate business of health insurance.

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The court reasoned, because the Act requires health plans to extend coverage to everyone regardless of pre-existing conditions, individuals could forgo health insurance until the need for medical care arose and at that point simply opt-in to a plan and in essence “game the system.” This would create a disproportionate burden and increase costs for those who prospectively opt for health insurance coverage prior to the actual need. Therefore, there is a rational basis by which Congress can require market participation in order to reduce the number of uninsured and minimize the “gaming of the system” by individuals not getting insurance until one needed it. If this was allowed the entire purpose of the act would be subverted. Therefore, because there is a rational basis for the individual mandate, the plaintiff has failed to meet its burden of proof in order to be granted an injunction. This case joins *Liberty Univ., Inc. v. Geithner*, --- F.Supp. 2d ---, 2010 WL 4860299 (W.D. Va. Nov. 30, 2010), as the second court to rule on the merits that the individual mandate is a proper exercise of congressional power under the Commerce Clause. This case has since been appealed by the plaintiff to the Sixth Circuit Court of Appeals.

*The individual mandate has been called the lynchpin to health care reform.*

#### **Eastern District of Virginia – Unconstitutional**

In *Commonwealth ex rel. Cuccinell v. Sebelius*, 702 F. Supp. 2d 598, 2010 U.S. Dist. LEXIS 77678 (E.D. Va., December 13, 2010) the court ruled that the individual mandate provision of the Act is unconstitutional, however this court severed the provision from the rest of the Act. The court did not rule the Act itself was unconstitutional, but only ruled on this particular provision of the Act. The Honorable Judge Hudson, found no pertinent case law that would extend Congress’s authority under the Commerce Clause or General Welfare Clause to encompass the regulation of an individual’s *decision* whether or not to purchase a product, notwithstanding the effect on interstate commerce.

#### **Northern District of Florida – Unconstitutional**

In *State of Florida, et al v. United States Department of Health and Human Services, et al.*, No. 3:10-cv-00091-RV-

EMT, (N.D. Fla. January 31, 2011) the Honorable Roger Vinson, granted the plaintiff’s motion for summary judgment, finding the Act in its *entirety* unconstitutional. First, the plaintiffs contended that the Act expands the Medicaid program and the state’s responsibilities to such an extent that it would make continued participation in the Medicaid program fiscally unsustainable, in violation of the Spending Clause of Article I Section 8 of the Constitution. Further, plaintiffs claimed that by creating this burden Congress has violated the Constitution and state sovereignty by coercing and commandeering the states, and depriving them of their “historic flexibility” to run their state government, healthcare and Medicaid programs.

Second, they also contend that the individual mandate and concomitant penalty exceed Congress’s authority under the Commerce Clause violating the 9<sup>th</sup> and 10<sup>th</sup> Amendments.

As to the challenge to the individual mandate, the court found that previous Supreme Court decisions all in some way regulated a form of activity in which an individual was engaged. As such, the court agreeing with reports from the Congressional

Research Service and the Congressional Budget Office found the notion of using the Commerce Clause to require individuals to purchase health care insurance to be unprecedented, and ultimately ruled that the individual mandate was an unconstitutional exercise of congressional authority. The court found that in order for the Commerce Clause to be the basis by which Congress is to exercise its power, there must be some sort of activity taking place. Here the court reasoned Congress is attempting to compel the actual activity itself and by those means there would be no limitation upon what Congress could regulate under the Commerce Clause. Finding that this was beyond the Founding Fathers original intent in drafting the Constitution and that the failure to purchase health insurance is not an activity, nor is the economic decision to forgo health insurance tantamount to activity for Commerce Clause analysis purposes, the court found the individual mandate exceeds Congress’ power and cannot be saved by application of the Necessary and Proper Clause, and thus is unconstitutional. However, the

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ruling goes even further. Because the individual mandate is the foundational basis for the virtually the entire Act, the court found the individual mandate provision could not be severed from the rest of the Act, because it is essential to the Act's implementation. Accordingly, the entire Act was found to be unconstitutional.

**What Does This Mean to You?**

In short, not a whole lot at this point. Prior to the Eastern District of Virginia and Northern District of Florida decisions, it was likely that the issue of the constitutionality of the individual mandate and possibly the entire Act would end up before the United States Supreme Court; now it is all but certain.

Further, it is important to keep in mind the level of authority that these rulings have. These cases were decided by Federal District Courts, meaning that these rulings are not "the law" in any other jurisdiction. For now, the rulings simply make for persuasive precedent, meaning that other district courts can choose to follow these decisions or ignore them completely. Eventually, this issue will likely come before the United States Supreme Court. However, any review by the Supreme Court is at least a couple of years away. Until then, the Act and the individual mandate provision should be treated as good law and all assumptions should be that both will remain in effect.

**Looking Ahead**

As discussed in *State of Florida*, the individual mandate has been called the lynchpin to health care reform. Without healthy participants being

actively involved by purchasing health insurance, there would be no practical way to require insurance companies to provide coverage to all individuals. The Act is based upon the premise that participants in good health will be paying for health care coverage (when they don't actively need it) and thus companies would be able to offset the costs of those participants in worse health (that have an active need for insurance coverage). Without the individual mandate, the Act as written may not be able to survive. Does this mean that you as a health care provider need not prepare for the pertinent changes applicable to your business in order to comply with Act? No, it does not. The individual mandate is not scheduled to take effect until 2014, and much can change between now and then. Further, as previously stated an ultimate ruling will not be had for at least a couple years and many of the provisions under the Act have already begun to require action on your part (i.e. - electing to grandfather a current plan) or will begin to require action in the new calendar year (i.e. - reporting requirements).

It would be imprudent to assume that the individual mandate and/or the Act will not survive, at least in some form. To make that assumption and to be incorrect could have very costly consequences. Even if the individual mandate were to be found unconstitutional by the Supreme Court there remains the possibility that the Act could be revised prior to its enactment in 2014. Alternatively, upon review the Supreme Court could alter the paradigm by which the Act is

currently being reviewed by redefining the reach of the Commerce Clause. For better or worse, the uncertainty surrounding the specifics of the individual mandate and the Act will be with us for the coming years. ■

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