

# KAMENSKY RUBINSTEIN HOCHMAN & DELOTT, LLP

Summer 2007 LAW UPDATE

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## **HEALTHCARE:** HANDLING HIPAA COMPLAINTS

Health Insurance Portability and Accountability Act ("HIPAA") complaints are generally of two types: (1) complaints by individual patients regarding violation of their HIPAA rights; and (2) complaints by office employees who use Protected Health Information ("PHI") regarding security problems that may put PHI at risk.

The practice must provide each patient with a Notice of Privacy Practices that includes:

- A statement of the right to file a complaint;
- A brief description of the procedure to follow to file a complaint with the entity and with HHS;
- The name and contact number of the contact person in the office; and
- A statement that no retaliation will result in the event of a complaint. Patients should be informed that complaints may be filed in one of two ways: (1) by mail or electronically through the Office of Civil Rights to the Secretary of Health and Human Services ("HHS"); or (2) directly to the practice. The latter route is preferable, as resolving the matter internally may avoid an HHS investigation. Individuals who file complaints or participate in any manner in an investigation must not be intimidated, coerced, threatened or retaliated against.

Under the Privacy Rule, each practice must have:

- A designated Privacy Official to develop HIPAA-compliant policies and procedures;
- A contact person who receives complaints and provides information
- Procedures to document all complaints and their disposition; and
- Formal procedures to respond to security incidents and to mitigate the harmful consequences of these events.

In a small organization, the privacy official and the contact person can be the same individual. Using the full response and report procedure may not be necessary in addressing every

complaint by individuals. While a formal investigation of a complaint may not be necessary, the following steps are required:

- Verify the facts;
- Take appropriate action;
- Notify the complainant of the actions taken; and
- Keep records of the complaint and its disposition for 6 years.

HIPAA also requires that employees report security incidents that may result in the improper disclosure of PHI to a security officer in the office, who may also be the person who served as the practice's privacy/complaint official. A practice must develop a formal reporting procedure which indicates: (1) what incidents employees must report and to whom; (2) the form of the report; and (3) the time period within which the report must be filed. Not only should actual security breaches be reported, but also breaches of the practice's PHI policies and procedures. The practice must also establish specific procedures to follow after the filing of a security report which specify: (1) who will investigate; (2) who will take remedial action; and (3) when disciplinary action is appropriate. The HIPAA Security Rule requires a progressive disciplinary policy against non-compliant employees to be in place. Reports of security incidents must also be retained for 6 years.

Practices must attempt to mitigate the potentially harmful effects of security incidents. They must take steps to ensure that the breach does not happen again and attempt to lessen the resulting harm. If identity theft could result, notification of both the injured party and law enforcement officials is appropriate. Except in cases of possible identity theft or unless a patient requests an accounting, the practice does not need to notify the patient of a security breach.

### **HEALTHCARE: ILLINOIS WHISTLEBLOWER REWARD ACT APPROVED BY FEDS**

The U.S. Department of Health and Human Services ("HHS") recently announced that Illinois' Whistleblower Reward and Protection Act qualifies the state for financial incentives under the Deficit Reduction Act ("DRA"). The DRA provides that if a state's false claims act meets enumerated criteria, the state will receive a 10% increase in its share of Medicaid fraud recoveries from state actions brought under the state's statute. To date, the HHS Office of the Inspector General has reviewed laws adopted in ten states, and Illinois law is one of only three state laws that satisfies the DRA's requirements.

The Illinois Whistleblower Reward and Protection Act (740 ILCS 175/1 et seq), is similar to the federal False Claims Act and imposes civil monetary penalties plus treble damages for filing false requests for payment to state agencies, including Medicaid. A private individual ("whistleblower") may bring a qui tam action for violation of the law in the state's name. If the state intervenes and the action is successful, the whistleblower will be awarded between 15% and 25% of the proceeds. After proceeds are disbursed to private individuals, the remaining funds are allocated to the Attorney General, the Department of State Police for law enforcement and to the state's General Treasury.

**HEALTHCARE: CON LAW REPRIEVE** On May 31, 2007, Governor Blagojevich extended the Certificate of Need program until August 31, 2008. The law requires that a task force study potential reforms of the CON program and make recommendations to the legislature by March 1, 2008. The legislation was approved almost unanimously by the Illinois House and Senate. The Certificate of Need program is designed to prevent unnecessary construction of health care facilities, while promoting cost containment, improved planning by health care providers and access to services based on community need.

**HEALTHCARE: HIPAA PRIVACY RULE: FOUR YEARS AND COUNTING** Four years after requiring Covered Entities to comply with HIPAA's "Privacy Rule," the Department of Health and Human Services has unveiled a website devoted to providing information on enforcement and compliance.<sup>[1]</sup> The website offers great insight into common violations and enforcement by the Office of Civil Rights (the "OCR").

The OCR has broad authority to investigate alleged Privacy Rule violations. As of April 2003, the OCR also has the ability to issue subpoenas when investigating an alleged violation. Should the OCR determine a violation occurred, it may request a violator to correct the practice or face civil monetary or criminal penalties. To date, however, the OCR has not recommended any civil monetary penalties. Since enforcement of HIPAA began, the Department of Justice (the "DOJ") has been referred 384 cases by the OCR related to the knowing disclosure of Protected Health Information ("PHI"); however, none have been prosecuted. The DOJ has prosecuted four violations where employees sold PHI for personal financial gain.

Overall, the OCR has received 26,408 complaints since April 14, 2003. As of June 2007, 5,931 are currently under investigation. 20,477 complaints have been closed after

preliminary review, or have been resolved after finding no violation or obtaining corrective action. The number of investigated complaints continues to trend upward, with 339 investigations in 2003 and 2,466 in 2006.

The violations most commonly alleged were the following:

1. Impermissible use and/or disclosure of PHI;
2. Failure to maintain procedures to safeguard PHI;
3. Lack of patient access to PHI;
4. Disclosing more PHI than is minimally necessary; and
5. Failing to obtain/inadequate authorization for disclosing PHI.

Generally, these complaints were most often directed at private practice physicians and general hospitals, followed by outpatient facilities, pharmacies and group health plans.

This data shows us that, while complaints and investigations are on the rise, both the OCR and DOJ appear willing to provide opportunity for a provider to become educated on the Privacy Rule and to correct their practices accordingly. It is only in extreme cases, such as when PHI is willfully mishandled for personal gain, where enforcement is required and penalties recommended. <sup>1</sup>[www.dhhs.gov/ocr/privacy/enforcement/](http://www.dhhs.gov/ocr/privacy/enforcement/)

### **INSURANCE: Workers' Compensation Insurance Requirements are Alive and Well - AND COULD COST YOU A BUNDLE!**

Recent work for several of our clients has reinforced the necessity of your making sure that all businesses, including medical practices that have employees maintain adequate workers compensation insurance.

Workers' Compensation Insurance covers employees if they are injured while on the job. Doctors offices, home health agencies, social service agencies and similar health care businesses which employ persons (other than the owners and certain high level employees which may be exempt) have always been required to purchase this insurance. Payment for injuries covered under workers' compensation insurance are determined according to a mandated state fee schedule, and claims are usually adjudicated by the Workers' Compensation Commission (the "Commission"), not by the courts. Both the premium rate and the risk of such injuries are relatively low in the health care industry, but nonetheless the requirement to purchase adequate insurance (or join a self-insurance pool) is still mandatory.

An employer who fails to purchase workers' compensation insurance risks significant penalties. There is a \$500 *per day* penalty for each day without adequate workers' compensation insurance. This can result in fines of hundreds of thousands of dollars even for a relatively small business with few employees (A company that does not have adequate insurance will be charged with any expenses an injured employee has). In addition, Illinois law provides a felony penalty for individuals who own or manage a company and who knowingly do not purchase adequate insurance. The financial penalties may be assessed not only on the company, but on the President and Secretary, and any other culpable officer. There is no minimum size for a business required to purchase insurance; any business of any size with any number of employees has to comply with the law.

Recent changes, both in the law (The Workers' Compensation Act, 820 ILCS 305/1 *et seq.*) and in the office of

at the Illinois Workers' Compensation Commission that enforces the insurance requirements, have resulted in much more aggressive enforcement of the requirement that every employer in Illinois maintain workers' compensation coverage. In addition, the creation of a national insurance database makes it easy for regulators to determine if a company has proper workers' compensation insurance. Governor Blagojevich has hired an aggressive ex-prosecutor to run the Commission, who is targeting, for the first time, health care businesses. The Commission has recently begun proceedings against several home health care agencies discovered to be non-compliant and is looking at a range of medical and provider businesses in the health care industry.

Contact us if you think your business may not be in compliance with the law. We have significant experience in negotiating the fines assessed by the Commission in cases of noncompliance and reducing or eliminating penalties. We can also help your business in connection with most issues relating to mandatory workers' compensation insurance.

--Phil Pomerance, June 2007

**HEALTHCARE:** "OIG ADVISORY OPINION 07-05: Selling Your Investment May be Costly." In a recent opinion issued by the Office of the Inspector General of the Department of Health and Human Services ("OIG"), the OIG was asked to review a proposed transaction where orthopedic surgeon ("Surgeons") who held a ninety-four percent (94%) interest in an Ambulatory Surgical Center ("ASC") would sell forty percent (40%) of their ownership interest to a local hospital. Although the amount to be paid by the hospital for the shares represented fair market value, the profit to be realized by the Surgeons would exceed the amount originally invested by the Surgeons for the same number of shares. The Surgeons did not offer to sell their ownership shares to any other buyers and the other ASC investors expressed no desire to sell their interests.

Because the hospital was in a position to make referrals to the ASC and/or the physician investors, the hospital agreed to limit its ability to make referrals in the following manner:

- Hospital would take no action to require or encourage medical staff to refer patients to the ASC or its investors, and would not track any such referrals;
- Compensation paid to any physician by the hospital would be based on fair market value and would not in any way relate to referrals to the ASC or its investors; and
- Hospital would continue to operate its own ASC.

Generally, the Medicare and Medicaid Anti-kickback Statute prevents knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce or reward referrals for items or services reimbursable by a Federal health care program. There are limited "safe-harbor" regulations defining transactions that are not subject to Anti-kickback regulations. With respect to ASCs, the safe-harbor provision requires, in part, that:

1. The terms of investment be unrelated to previous or expected volume of referrals, services furnished or amount of business;
2. The amount payable to an investor in return for the ASC investment must be directly proportional to the amount of the capital investment;

3. An investor hospital must not be in a position to directly or indirectly make or influence referrals to the ASC; and

4. Physician investors who are in a position to make referrals to the ASC must meet specific requirements for ASC ownership, related to whether the ASC is surgeon-owned, single-specialty or multi-specialty.

In its opinion, the OIG reiterated its concerns regarding joint venture arrangements by those in a position to refer business since such arrangements pose an increased risk that the income from such ventures will be payment for referrals to the venture or investors. The OIG found the proposed transaction did not qualify for safe-harbor protection and posed at least minimal risk under the Anti-kickback statute. Although the Surgeons' return on investment was directly proportional to their ownership interest, the hospital would pay more per ownership share than the Surgeons paid initially and the Surgeons would receive a higher rate of return on their remaining shares than the hospital would receive on its newly-purchased shares.

Moreover, the OIG found that it could not sufficiently determine that the proposed transaction was not motivated by reward or influence. In reaching this conclusion, it noted that only some physician investors were selling their shares at an appreciated price," and that the money to be paid would directly benefit the Surgeons and not be used to invest in the expansion or enhancement of the ASC itself. The OIG found this raised the possibility that the Surgeons were being rewarded by the hospital for valuable referrals to the ASC or hospital. Taking all facts and circumstances into account, the OIG found it could not conclude that a difference in cost of capital acquisition which resulted in financial gain to the Surgeons in a position to make valuable referrals was unrelated to the volume of referrals or business generated between the parties.

In light of this Opinion, parties to similar transactions should be advised that simply paying fair market value for an ownership interest may not be enough to prevent regulatory scrutiny if there has been an appreciable increase in an ASC's value since initial investment, or if only a portion of investors are involved in the transaction. In this regard, it will be even more critical when entering similar transactions to give clear indication of intent to not base any from of remuneration on referrals or generated business.

### **KRHD NOTES**

**Alon Stein** was elected to the Illinois state Bar Association's Assembly.

**Christina M. Kuta** joined the firm as an associate in 2007. Her prior legal experience includes working as a contract attorney for a major Chicago law firm, as well as clerking for the Honorable David D. Noce, United States District Court for the Eastern District of Missouri. Christina is a member of the Firm's health care department and concentrates her practice in the area of regulatory and transactional health care. Ms. Kuta has been admitted to practice law in the state of Illinois, and is a member of both the American Bar Association and Illinois State Bar Association.

Ms. Kuta received her law degree, *Summa cum Laude*, from Southern Illinois University School of Law in 2003, where she was the Lead Editor of the *Southern Illinois University Law Journal*. Ms. Kuta received her LL.M. in Health Law in 2004

from Saint Louis University School of Law. She received her M.S.W. degree, specializing in Health Policy, from the University of Illinois at Urbana-Champaign in 1998, and her B.S. degree in Psychology from the University of Illinois at Urbana-Champaign in 1996.

**HEALTHCARE: Internet Medical Practice in Illinois and Indiana** An estimated forty percent (40%) of adults report the internet has helped them cope with a major illness, while fifty-four percent (54%) report the internet has helped them assist another person in coping with illness. Pew Internet & American Life Project, John Horrigan and Lee Rainie, The Internet's Growing Role in Life's Major Moments, (April 19, 2006). Given these statistics, it is not surprising that many physicians see the benefit to using the internet in carrying out their medical practice. To use this valuable practice tool, it is important to recognize physicians may have to navigate one more set of rules in a sea already filled with regulations.

In Illinois, the Illinois State Medical Society's 2007 Legislative Agenda seeks to amend current regulations to add criteria for the practice of internet prescribing. First, there must be an established relationship evidenced by documented patient evaluations. Second, the physician and patient must clearly discuss treatment options and risk. Lastly, the physician must maintain medical records. The proposal further seeks to provide exemptions in emergency situations, in consult with other health care professionals, in on-call consultations, for admissions orders, with respect to orders for patients in long-term care facilities or hospitals, or for continuing medication for a new patient prior to the first appointment, but only for a limited period of time.

In Indiana, physicians engaging in internet medical practice can rely on its State Medical Board for guidance. In Rule 3, 844 IAC 5-3-1, the Board requires that physicians have a documented patient evaluation, including history and physical, before providing treatment electronically and specifically prohibits prescribing medication based on internet questionnaires or consultations. Physicians must further maintain written policies related to the use of electronic service and patient privacy and security, and patients must give written consent for "patient-physician e-mail." Further, the patient's medical record must contain copies of any electronic communications.

While the internet can be a valuable tool for a medical practice, given the regulatory implications, physicians should consult counsel before engaging in any form of internet medical practice.

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