

**\*\*CLIENT ALERT\*\***

**The Office of Civil Rights starts HIPAA audits**

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

It's time to assess your HIPAA compliance and determine whether you have adequate policies and procedures in place and whether they are being followed.

The Office of Civil Rights (OCR) of the Department of Health and Human Services, which is the enforcement agency for HIPAA compliance, will begin audits to assess covered entities' compliance with the privacy, security and breach notification rules.

Consulting firm KPMG has contracted with OCR (in a \$9 million dollar contract) to develop audit protocols and will conduct up to 150 audits, beginning this month through the end of 2012.

OCR will notify in writing covered entities selected for an audit. OCR has not provided an explanation for its selection criteria. The notification will explain the program and describe initial document and information requests, which should be provided within 10 business days. Selected covered entities can expect a site visit between 30 and 90 days after notification.

It is anticipated that OCR will use resulting audit reports to determine types of technical assistance that should be developed and the types of corrective action that are most effective.

*If you have any questions concerning HIPAA compliance, and the upcoming audits, please contact Diane Kutzko. She can be reached at [dhk@shuttleworthlaw.com](mailto:dhk@shuttleworthlaw.com). ■*



**Adverse events:  
Disclosure is a process**

by Connie Alt [cma@shuttleworthlaw.com](mailto:cma@shuttleworthlaw.com)

Disclosure is a process that starts even before an adverse outcome occurs. It ends with being ready to say "I'm sorry and I'm ready to rectify our error," if the shoe fits. The following is an outline of a disclosure process. It provides some very good reminders and tips from those of us who see the patient/family reactions to adverse events on a daily basis. It is not, however, a substitute for a true Disclosure Program at your office or institution. If you have not implemented a Disclosure Program, we strongly recommend that you consider a program, including onsite training to get your organization prepared to take full advantage of its benefits. Please feel free to call any member of the Shuttleworth & Ingersoll Health Law team regarding program implementation and on-sight training sessions.

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1. **Pre-event groundwork**
  - a. Build a trusting open relationship with patient/family.
  - b. Give more than lip service to informed consent process.
2. **Initial disclosure.** An event has occurred. You do not know more than that. Initial disclosure is about communication. The goal is to open up the lines of communication. Don't let the patient or family feel abandoned.
  - a. **Immediately** meet with the patient/ family.
    - i. Have two (2) people together communicate with patient/family.
    - ii. Best options include person with close relationship with the patient, and risk management, or another manager with experience and a level head.
    - iii. But don't wait for the "best" people if they are not readily available. Many should be trained to carry out this first step so it can be done immediately.
  - b. Express **recognition** and **empathy** but not fault. "We know this happened and we are sorry you have pain as a result."
  - c. Promise that the risk management representative will be in contact within 24 hours.
3. **Interim Step.** Take a deep breath and together with risk management, prepare a plan of action.
  - a. Make a plan to access and take care of immediate needs of patient/family.
  - b. **Tell the patient/family what you are going to do.** Assure the patient/family that you will investigate and report back your findings promptly.
    - i. **Set expectations and meet them!!** "Promptly" doesn't necessarily mean tomorrow. Tell them how long it will be before you re-contact and keep your word.
    - ii. **Do not promise someone's head.** Not every bad outcome is someone's fault. Tell them that from the outset, but let them know you will be honest if there is someone who should have responded differently.
    - iii. Do not speculate as to what happened or why before you investigate.
  - c. Keep notes regarding your initial meeting, your disclosure, that you expressed empathy, would investigate, and advised that there may or may not be something that could have been done differently to avoid the event. Be factual in documentation. These notes would not be in the medical record but in a risk management file on the incident. Whether you make any reference in the medical record to the meeting is up for debate, but if you do, be very factual and brief (i.e. Administration of penicillin discussed with patient and son).
4. **Investigation**
  - a. Involve your risk management department, your insurance representatives, your department chairs as necessary.
  - b. Outline for yourself what needs to be done and who will do it.
  - c. Set a timetable for completion, keeping in mind what you have promised the patient/family.
  - d. Consider outside review.
  - e. Whatever else you do, keep your promise to the patient/family on when you were going to get back.
5. **Disclosure of Investigation Results and Resolution**
  - a. Share the results of the investigation
    - i. Plan ahead – who will be present, where will you meet.
    - ii. Plan what you will say, and what records you will show them to explain the conclusions. Do not refer to peer review or advice from counsel.
    - iii. Contact the patient/family; you may want to invite them to bring their advisors (this may mean their relative who has medical knowledge and has given them some questions, or you may know that they have an attorney involved).
  - b. If there was a mistake, apologize, admit fault, and explain what happened and how you are going to prevent it from happening in the future, as well as offering to discuss fair compensation. **This will require the prior approval of your insurance carrier and must be done with their knowledge and approval.**
  - c. If there was not a mistake, be fully open and upfront with the findings and why you do not believe the bad outcome resulted from fault. If this event was covered well in a pre-procedure informed consent it may be a good time to bring up the consent form and relate the result. ■

# Formal compliance programs will become increasingly important: Are you ready?

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

## Background

In the late 1990's the government, specifically the Office of Inspector General, launched an initiative to encourage health care providers to adopt "voluntary" compliance programs. The stated effort was to prevent the submission of erroneous claims and to combat fraudulent conduct on the part of health care providers.



Whether or not a particular provider had a compliance program in place was one factor taken into account during investigations of provider conduct and enforcement of laws targeted to fraud and abuse.

Since the late 1990's, the general focus of compliance efforts included (and will certainly continue to include) billing practices (including coding appropriately and avoiding upcoding); documentation to support submission of claims; medical necessity; and scrutiny of relationships with other providers (physicians, hospitals, nursing homes, vendors) to determine whether those relationships involved payments based on the volume and value of referrals.

As part of the Affordable Care Act, the government has upped the ante with regard to compliance programs. Under the Act, providers that bill to Medicare will be *required* to have written compliance policies. At the present time, no timetable has been set, except for Medicare skilled nursing facilities and Medicaid nursing facilities which are required by March of 2013 to have adopted a formal compliance program consistent with rules that are to be promulgated by March of 2012.

The Affordable Care Act increased funding for fraud and abuse enforcement activities by an additional \$250 million dollars for the next six years. In addition, the Recovery Audit Contractor program (RAC audits) continue in Iowa and elsewhere. Implementation of effective compliance programs is in light of increased

efforts to detect fraudulent provider practices (as well as waste and abuse of the federal payer systems).

## What will the requirements of a mandatory plan look like?

The Department of Health and Human Services has identified eight core elements for a nursing facility compliance program (with final regulations coming out by March of 2012):

- i. Compliance standards and procedures must be adopted and followed.
- ii. Specific individuals with authority and sufficient resources must be assigned to oversee compliance.
- iii. The organization must exercise due care to ensure that compliance authority is not delegated to an individual with a propensity to engage in criminal, civil or administrative violations.
- iv. The organization must take steps to educate its employees and agents concerning the compliance program.
- v. The organization must take reasonable steps to achieve compliance with its standards.
- vi. The standards and procedures must be consistently enforced.
- vii. If an offense is detected, the organization must respond appropriately and prevent similar offenses.
- viii. The organization must periodically reassess the compliance programs and make changes necessary to reflect changes within the organization.

It is anticipated that other mandatory programs may contain the same elements.

## We have had a compliance plan in place for many years— is that enough?

Many providers implemented compliance plans consistent with "Guidances" issued by the Office of Inspector General starting in the late 1990's. These can be found at [www.oig.hhs.gov/compliance-guidance/index.asp](http://www.oig.hhs.gov/compliance-guidance/index.asp). While it is anticipated that the requirements

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of mandatory compliance programs will share many of the elements of those voluntary plans described in the Guidances, there may be some new specific requirements, including mandatory reporting requirements and accountability directly to the governing body of an organization.

If you have a Compliance Plan, now is the time to pull it out and review. Here are some questions to consider:

- a. Is the Compliance Officer appropriate and effective – does she or he have direct reporting duties to the CEO and Board?
- b. How often do you perform internal audits of billing and documentation practices?
- c. How do you handle complaints?
- d. Is there anonymous reporting and an anti-retaliation policy?
- e. Have you reviewed (or do you review on an ongoing basis) contracts with other health care entities to determine whether they are consistent with federal and state laws governing such transactions?
- f. Are you educating your staff and governing body concerning their duties on an ongoing basis.

**We have never implemented a formal compliance plan – should we do it now or should we wait until the Department of Health and Human Services issues regulations concerning a mandatory compliance program applicable to us?**

Given the enforcement climate, it is critical that you are aware of your duties to comply with federal (and

state) laws that apply to you. Compliance programs provide a method and vehicle for determining whether you are in compliance now and a means for monitoring compliance with billing requirements, documentation requirements and prohibitions against self referrals and basing compensation and other payments on the volume and value of referrals. Accordingly, you should undertake now to appoint a Compliance Officer, consider internal auditing (if you do not already) of billing and documentation practices, and a review of your contracts (including leases for real estate and equipment). And you should proceed to put together policies and procedures consistent with these steps, as well as providing a mechanism for investigating complaints and a plan for what you will do in the event you find that you are out of compliance.

**We are a very small physician practice. Do we need a formal plan?**

The answer is yes. The issues that confront large practices – billing, documentation, and avoiding illegal contracts – also affect you and potentially expose you to civil and criminal penalties. The Office of Inspector General recognized that the needs of solo or small practices are different than large ones in issuing a “Compliance Program for Individual and Small Group Physician Practices,” (see [www.oig.hhs.gov/compliance-guidance/index.asp](http://www.oig.hhs.gov/compliance-guidance/index.asp)) and presumably the mandatory plan for such practices will take size into account as well.

*If you would like further information concerning compliance programs, contact Diane Kutzko, Chair, Health Law Practice Group. She can be reached at [dhk@shuttleworthlaw.com](mailto:dhk@shuttleworthlaw.com) or 319-365-9461. ■*

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