# Patient Safety Law Presents New Challenges

*The system will create a searchable database that can be used to prevent similar errors in the future.*

BY NELLIE BRISTOL
*Contributing Writer*

WASHINGTON — The patient safety system signed into law this summer by President Bush will likely take many months to implement—and is likely to demand some adjustment in physician attitudes about error reporting.

Under the new law, a "patient safety work product" of reported errors and near misses is privileged and cannot be used in legal or disciplinary actions. Data collected can be used in a criminal trial only after the court makes a determination that the evidence is "material to the proceeding" and "not reasonably available from another source," according to text of the Patient Safety and Quality Improvement Act of 2005.

This structure will allow providers to voluntarily submit information to patient safety organizations that have been certified by the Department of Health and Human Services. Patient confidentiality must be maintained.

The purpose of the patient safety system is to create a searchable database of medical errors that can be analyzed and used to develop new care systems and best practices that would help prevent similar errors in the future.

The law authorizes federal funding for fiscal years 2006-2010. Implementation could begin as early as next year, said Gordon Wheeler, associate executive director for public affairs for the American College of Emergency Physicians, noting that for that to happen, the HHS "secretary's got a lot to do to set it up."

HHS must coordinate databases nationwide into a single aggregated interactive resource for providers and patient safety organizations. It also must develop or adopt voluntary national standards to promote the electronic exchange of health care information.

HHS will also certify the organizations, which were described as "new animals," by Margaret VanAmringe, vice president for public policy and government relations at the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

There are several possible models for patient safety organizations, she said, including U.S. Pharmacopeia's MEDMARX system. For a subscription fee, hospitals and health care systems can access MEDMARX's database to track adverse drug reactions and medication errors. Ms. VanAmringe also said groups like JCAHO could develop patient safety organizations, as could medical specialty organizations looking to establish 'niche patient safety organizations' to track specific areas, such as anesthesiology.

For physicians, who have operated so long in an environment characterized by liability fear, it may take a while to trust the new system, said Michael O. Fleming, M.D., board chair of the American Academy of Family Physicians.

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**DR. FLEMING**

"Physicians are going to have to get comfortable with this and realize that [documenting errors under the plan] is a thing that you can do now, and it's going to improve quality tremendously," said Dr. Fleming, adding that it may take physicians some time to lose their reporting inhibitions.

Doctors are concerned about reporting something going wrong, because someone will be at fault and liable for that situation, he said. "In medicine, unfortunately, too many times everybody—from staff to nurses to doctors—has been afraid to report things."

Dr. Fleming said the arrangement could help reveal weaknesses in medication dispensing and other systems. "This will give us an opportunity, when these errors occur, to report them without having to worry about the consequences of a liability threat," he noted.

Many patient safety organizations will most likely be run by systems analysts and industrial engineers, "I'm hoping there are also going to be peers," Dr. Fleming said. "I think physicians are going to feel much more comfortable if we have peer evaluation."

Ms. VanAmringe said patient safety organizations will not only need to collect data but also have the ability to aggregate and analyze those data to provide institutions with "feedback on common problems." The patient safety organizations (PSOs) will develop solutions and best practices by collating data from different institutions and then monitoring whether proposed interventions work.

"PSOs will play a fairly robust role in using the data that are reported to them," she said.

Federal patient safety organizations will not preempt state laws, even those with mandatory reporting systems, but VanAmringe said many state arrangements are more narrowly focused and do not provide the data analysis expected from federal patient safety organizations.

The federal program will provide standardized reporting methods and more in-depth, comprehensive analysis. In addition, the federal system has the potential to develop more solutions to common problems, Ms. VanAmringe said. ■

# Develop a Proactive HIPAA Complaint Process, Lawyer Advises

BY ELAINE ZABLOCKI
*Contributing Writer*

SAN DIEGO — Health care organizations need a proactive process in place to deal with Health Insurance Portability and Accountability Act complaints, Teresa A. Williams, in-house counsel for Integris Health Inc., said at the annual meeting of the American Health Lawyers Association.

Having an effective complaint process in place could reduce the number of complaints patients file with government enforcement agencies.

At present, HIPAA enforcement is primarily complaint based, Ms. Williams said. During the first year of enforcement, 5,648 complaints were filed with the Office for Civil Rights (OCR), according to a report published by the Government Accountability Office.

Of those, about 56% alleged impermissible use and disclosure of protected health information, about 33% alleged inadequate safeguards, and about 17% concerned patient access to information. (Percentages total more than 100 because some complaints fall into more than one category.)

As of June 30, 2005, OCR has received more than 13,700 complaints, and has closed 67% of those cases. They've been closed because the alleged activity actually did not violate the privacy rule, or because OCR lacks jurisdiction, or because the complaint was resolved through voluntary compliance. To date, OCR hasn't actually imposed any monetary penalties.

OCR is making every effort to resolve potential cases informally. Ms. Williams gave an example from her company.

Last fall, a patient at one of Integris Health's rural facilities filed an OCR complaint alleging her son's health information had been improperly disclosed. Within 2 days, Integris was able to confirm, through an audit trail, that this had in fact happened, and the responsible employee was terminated.

OCR then requested a copy of the explanatory letter sent to the complainant, records showing that the employee had received appropriate training about HIPAA, and written evidence of termination. "It was all very informal, just a series of phone calls and letters back and forth," Ms. Williams said. "It took only about 2 months for our case to be closed."

Ms. Williams advises health care organizations to put a strategy in place for handling potential HIPAA complaints. Key steps:

- ► Train staff on appropriate records and documentation.
- ► Develop and enforce discipline policies.
- ► Conduct patient satisfaction surveys.
- ► Conduct training to inform staff about appropriate uses and disclosures of protected health information.
- ► Take corrective action if necessary, then document it.
- ► Use information gained from the complaint process to better your system.

A variety of methods may be used to process complaints. These methods include written complaint forms, a hotline, a privacy officer, regular mail, e-mail, and online forums.

There is one key element: The person in charge of the complaint process should be able to listen and respond with empathy to the patient.

"Sometimes people aren't looking for a monetary resolution," Ms. Williams said. "They just want someone to listen to their complaint and tell them that it's been corrected." ■

## HIPAA Rule Has 'Worrisome' Provision

The final installment of the HIPAA enforcement rule was released on April 18, 2005. Civil monetary penalties are set at a maximum of $100 per violation, up to a maximum of $25,000 for all violations of an identical requirement per calendar year.

But a single act can create multiple violations, Ms. Williams pointed out. That's because the rule uses three variables to calculate the number of violations that have occurred:

- ► The number of times a covered entity takes a prohibited action or failed to take a required action.
- ► The number of persons involved or affected.
- ► The duration of the violation, counted in days.

Under the new rule, information about civil monetary penalties, including reason for the penalty and identity of the covered entity, will be made available to the general public. It is not clear whether this happens when the penalty is first imposed, or after legal appeals are completed.

"This provision is a bit worrisome," Ms. Williams said.

If an emergency department over a 3-month period doesn't collect and file written acknowledgments of privacy notifications, that would count as numerous violations of the privacy rule.

"If a consumer then reads in the paper that your hospital paid hundreds of thousands of dollars for a thousand violations of the privacy rule, that's arguably misleading," Ms. Williams said. "This is an area that hopefully will be clarified and changed."