

Proactive Process Urged for HIPAA Complaints

More than 13,700 complaints have been filed, but no monetary penalties have been imposed thus far.

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 during 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

Enforcement Rule Called 'Worrisome'

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:

- ▶ 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, however, whether this happens when the penalty is first imposed, or after legal appeals are completed.

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

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 have a strategy for handling potential HIPAA complaints.

Key steps include:

- ▶ 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.

Methods to process complaints include written forms, a hotline, a privacy officer, regular mail, e-mail, and online forums.

One key element: The person in charge of the complaint process should be able to listen and respond with empathy. ■

Drug Industry Ad Guidelines Draw Criticism

BY JOYCE FRIEDEN
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New voluntary guidelines for direct-to-consumer prescription drug advertising that were released by the Pharmaceutical Research and Manufacturers of America have drawn criticism from politicians and consumer groups who say they do not go far enough.

"While I wish the PhRMA guidelines would have gone farther and proposed a moratorium on DTC [direct-to-consumer] advertising of newly approved drugs, I hope individual pharmaceutical manufacturers will seriously consider such a measure," Senate Majority Leader Bill Frist, M.D., (R-Tenn.) said in a statement.

Sidney Wolfe, M.D., who is the director of the Public Citizen



Health Research Group, called the PhRMA announcement "a meaningless attempt to fool people into believing the guidelines are stronger than they really are."

The guidelines were released in Dallas in early August at a meeting of the American Legislative Exchange Council.

Among other things, the guidelines call for pharmaceutical manufacturers to educate physicians and other health care providers about new drugs before advertising them to consumers.

"The centerpiece is the notion that the companies are committing an appropriate amount of time to educate health care professionals about new medications and new indications ... to make sure physicians and other providers know about the medicines and benefits before" direct-to-consumer advertising campaigns are undertaken, Billy Tauzin, who is the CEO of PhRMA and a former congressman from Louisiana, said during a press conference that was sponsored by PhRMA.

The length of time the companies will take to educate physicians will depend on several

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DR. FRIST

factors, including whether the drug is a life-saving one and how complex the risk-benefit profile is, Mr. Tauzin said. "We are also committed to continuing to educate health care professionals as additional info about a medication is obtained from all sources, even after medication has begun being marketed."

Other provisions of the voluntary guidelines, which 23 companies have signed onto, include:

- ▶ DTC ads should be balanced, and discuss the benefits and risks of the medication. The information should be presented in "clear, understandable language, without distraction from the content."

- ▶ Ads should be targeted to avoid audiences that are not age appropriate. For example, Karen Katen, president of Pfizer Human Health, said that her company would not run a television advertisement for Viagra (sildenafil) during the Super Bowl, when young children may be watching.

- ▶ Companies should submit new DTC print and television advertisements to the FDA before releasing them. PhRMA board chair Bill Weldon said this does not mean that companies would submit an ad to the FDA on Tuesday and then run it on Wednesday. "The intent is to make sure that FDA has been able to comment on any programs prior to advertising," said Mr. Weldon, who is also chairman and CEO of Johnson & Johnson.

- ▶ Ads that identify a product by name should include the product's indications as well as its risks and benefits. This means no more ads that just give the name of the medication and tell what it's for, Mr. Tauzin said.

PhRMA also will convene an independent board in about a year to get outside opinion on whether the companies are following the guidelines. The panel will include experts in health care, broadcasting, and other relevant disciplines.

The panel's report "will be made public, and also made available to the FDA," Mr. Tauzin said. ■

The voluntary guidelines are available at www.phrma.org/publications/policy/admin/2005-08-02.1194.pdf.

Clinic Experience Influences Medical Students' Attitudes

ST. PETE BEACH, FLA. — Attending a specialized clinic for pregnant women with substance use disorders helped medical students in a recent study feel more comfortable and less judgmental when working with such patients.

A total of 104 consecutive third-year students rotating on an 8-week obstetrics-gynecology clerkship were enrolled in the study and randomized to attend or not to attend the half-day clinic. Responses to a 36-item survey administered at the start of participants' clerkship and midway through the clerkship showed significant improvements in the comfort level of clinic attendees in regard to talking with patients about smoking, alcohol use, and other substance use, William A. Ramirez-Cacho, M.D., of the University of New Mexico, Albuquerque, and colleagues reported in a poster that was presented during the annual meeting of the Teratology Society.

The responses also demonstrated that the clinic attendees were significantly less judgmental of patients with substance use disorders and significantly more aware of multidisciplinary therapy approaches for treatment.

Control students' survey responses indicated a significant decline in comfort level when it came to discussing patients' habits, and a significant decline in awareness regarding how common substance use disorders are in this population, the investigators noted.

—Sharon Worcester