Top 10 Ways to Avoid Federal Fraud Prosecution

BY JOYCE FRIEDEN
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BALTIMORE — There are 10 things physicians can do—or avoid doing—to help protect themselves from federal prosecution for fraud, D. McCarty Thornton said at a forum sponsored by the American Health Lawyers Association.

Mr. Thornton, formerly chief counsel at the Office of Inspector General (OIG) at the U.S. Department of Health and Human Services and now an attorney in private practice, offered his "Top 10" in reverse order:

10 **Personal favors to referral sources are over.** That message was reinforced by both the TAP pharmaceutical lawsuit and OIG's recent guidance to pharmaceutical firms regarding proper marketing techniques, he said. "This means no NFL tickets, no fancy dinners, nothing for spouses, no free computers, and don't put strings on any kind of 'educational grant.' "

9 **Don't be the low-hanging fruit . . .** The number of federal agents investigating fraud is declining, so each agent has stacks of potential cases to choose from. "You don't want to stick out" by being an outlier on claims or engaging in other questionable behavior, he noted.

8 **. . . But also be wary of being in the crowd.** Don't go along with any questionable behavior simply because large groups of people are doing it. "Common sense is a lot of it," Mr. Thornton said.

7 **If you are mulling over a business deal, consider whether it will pose a problem under the anti-kickback statute.** "The further the deal is away from clinical decision making, the more leeway you have under the kickback statute, because the number-one purpose of the statute is to prevent the corruption of medical decision making," he said. "If the deal concerns office software for billing or practice management, it doesn't really affect where or how clinical decisions are made, and you have a lot more leeway under the kickback statute."

6 **Get as close to a safe harbor or advisory opinion as possible.** "Document the business reasons why you can't fully comply with the safe harbor," he said. "And you adopt the principles in the relevant OIG guidance to the extent you can. There is more written guidance from the anti-kickback statute—by far—than on any other criminal statute in the U.S. Code . . . the OIG has spoken on a lot of the issues involved."

5 **Consider fair market value of the "safe unharbor."** Using fair market value in all transactions "provides excellent overall protection" from fraud allegations. Fair market value should be used for necessary, justifiable services, and it should be determined "by an independent, reliable source using recognized methodology," he said.

Mr. Thornton noted that fair market value "never will be a safe harbor, because the government doesn't want to get into a 'Battle of the Experts' about your valuation experts [versus] their valuation experts, but it still is the basic talisman for safety under the anti-kickback statute."

Be sure to check compliance on an ongoing basis; confirm that deals are properly implemented and everyone involved is fulfilling their responsibilities.

4 **Don't muddy your own shoes.** "No fooling around with documents or withholding information," Mr. Thornton admonished. "And don't ask for the 'odds' on getting caught" with a particular scheme.

3 **Check compliance on an ongoing basis.** "Make sure deals are properly implemented" and that everyone involved is fulfilling their responsibilities, Mr. Thornton said.

2 **Document, document, document.** "Document that the deal is for legitimate business purposes, that it's at fair market value, what services are provided, and how much time is spent providing them," he said.

1 **Greed is good—not.** "The number-one red flag to investigators is a return on investment or compensation that seems excessive," he said.

Mr. Thornton had some advice for hospital compliance officers, warning them about the use of 'economic credentialing.' "Requiring a minimum level of practice to ensure proficiency is fine, but asking the doctor to refer 50% of his patients is going too far," he said.

He also warned physicians to be careful about what they accept from pharmaceutical companies. Despite recent guidelines on the subject, "some doctors are still being led astray by being paid hundreds of dollars for filling out a simple form," he said.

"We still have serious issues out there, and doctors need counseling and education," he added. ■

Tort Reform Should Address Reasons Why People Sue

BY MARY ELLEN SCHNEIDER
Senior Writer

ALEXANDRIA, VA. — Traditional tort reform measures like damage caps won't address some of the fundamental problems with the medical liability system, experts said at a meeting on patient safety and medical liability sponsored by the Joint Commission on Accreditation of Healthcare Organizations.

To deal with the current malpractice situation, the medical community needs to address the reasons why people sue—injuries, unmet expenses, and anger, said Lucian L. Leape, M.D., of the department of health policy and management at the Harvard School of Public Health, Boston.

"The main reason most people sue is because they are angry at the physician," Dr. Leape said.

But the current system and the most commonly proposed reforms, such as damage caps, don't address the need to increase disclosure of errors to patients or incentivize physicians to offer apologies, he said.

In the current tort system, filing a lawsuit is often the only way that patients feel they can get information about what happened to them or impose a penalty on the physician, said Michelle Mello, Ph.D., also of the department of health policy and management at the Harvard School of Public Health.

But this process often fails to secure an admission of responsibility or an apology, she said.

Traditional reforms such as caps would undercompensate seriously injured patients and increase administrative costs, Dr. Mello said. But they would not help deter medical malpractice, she said.

Damage caps also fail to address the poor correlation between medical injury and malpractice claims, she said. Instead of focusing on caps, the medical community needs to consider an administrative compensation system to replace torts.

The malpractice system is "blocking efforts at patient safety," said Troyen A. Brennan, M.D., professor of medicine at Harvard Medical School, Boston, and professor of law and public health at the Harvard School of Public Health.

A new system should be established to separate compensation for injuries from deterrence, he said. In order to do that, liability for negligence has to be eliminated, and reporting has to be made based on patient injury.

"You have to enable open and honest reporting," Dr. Brennan said.

And physicians have to realize that reporting patient injury is part of their professional responsibility, he said.

Currently, some physicians do not disclose errors or injuries. It's a rational economic response to their rising premiums and fear of being sued, he said, but it's not an ethical response. ■

U.S. Pharmacopeia Finalizes Model Guidelines for Drug Plan Formularies

The standard-setting group U.S. Pharmacopeia has established 146 unique therapeutic categories and pharmacologic classes to guide the establishment of formularies under the new Medicare Part D prescription drug benefit.

The model guidelines created by USP will serve as a voluntary framework for health plans and prescription drug plans as they create drug plan formularies for Medicare, as established by the Medicare Modernization Act of 2003.

"The model guidelines are not a formulary," said Roger L. Williams, M.D., USP executive vice president and CEO and chair of the group's Model Guidelines Expert Committee, said in a press teleconference.

The group also created a separate listing of formulary key drug types to help the Centers for Medicare and Medicaid Services assess the comprehensiveness of proposed formularies.

Under proposed Medicare regulations, plans that follow the model guidelines would need to offer at least two drugs in each therapeutic category and pharmacologic class. USP has recommended that CMS require plans to offer at least one drug from the list of formulary key drug types or have a clinical or scientific rationale for excluding the drugs.

CMS officials will use the guidelines to help evaluate proposed formularies.

After USP issued draft guidelines for evaluating proposed formularies last August, physician groups and patient advocates complained that too many critical drugs were in a third category, where they would not be required to be covered.

The final guidelines include a new therapeutic category for inflammatory bowel disease agents and a new pharmacologic class for proton pump inhibitors. Other changes include additional antidementia drugs and expanded dermatologic agents.

Dr. Williams said he hopes all parties will see this as "workable compromise."

The National Mental Health Association (NMHA) warned that the USP guidelines ignored recommendations from the mental health field not to group older medications with newer therapies. The association said that because these different medications are lumped together, health plans could choose to cover only the older, less expensive drugs. But NMHA president and CEO Michael M. Faenza said in a statement that his group is encouraged that CMS plans to consider widely accepted treatment guidelines for mental health when reviewing formularies.

But America's Health Insurance Plans (AHIP) praised the USP's final document.

"The final model continues to provide needed flexibility by not expanding the number of categories and classes previously proposed," said Karen Ignagni, AHIP president and CEO. "The direction that CMS is clearly taking supports the building of effective private plan strategies to make the Part D benefit clinically appropriate and affordable for Medicare beneficiaries."

Officials at the Pharmaceutical Research and Manufacturers of America, which has supported access to a broad array of treatments, were still reviewing the document at press time.

—Mary Ellen Schneider