Sunshine Act reporting has implications for malpractice litigation

Under The Physician Payment Sunshine Act, manufacturers of drugs, devices, and biological and medical supplies are required to report payments made to physicians to the Centers for Medicare and Medicaid Services. This data, once it is posted on a public website in September 2014, could help plaintiff attorneys to strengthen malpractice claims.

"Many physicians and practice managers do not realize that the net is very broad. Even being taken out to lunch is going to be reportable," says **William M. Mandell**, JD, an attorney with Pierce & Mandell in Boston.

A plaintiff attorney could argue that a physician's relationship with industry is relevant to a claim that the physician committed professional negligence. "In some malpractice cases, there could be an inference or circumstantial evidence that the physician's independent judgment was clouded by financial relationships," says Mandell.

Nothing in the statute or the implementing rules prevents the data from being used in court. "So, the information will be out there, and it really all just depends on the rule of relevancy," says **Christopher Robertson**, PhD, JD, associate professor at the University of Arizona's James E. Rogers College of Law in Tucson.

While the easy availability of the database will increase the likelihood of plaintiffs' attorneys checking it as part of their due diligence investigation of a claim, says Robertson, "in another sense, there is nothing new here."

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Even before the act, a plaintiff's attorney could have always gotten the information through civil discovery by asking about it at deposition, requesting production of documents, or via subpoena to the manufacturer. "There is a wealth of publically accessible data already on physicians and industry," says Mandell. "Many of the larger pharmaceutical companies, as part of settlements with the government on false claim cases, or even voluntarily, have put up their data to get ahead of the curve."

Some states have had transparency laws in place for several years requiring manufacturers and distributors of pharmaceuticals and devices to report certain transfers of value of payment to doctors licensed in the state.

"The Sunshine Act is not necessarily going to be that revolutionary or dramatically different than what's already been publically accessible, but will be a more comprehensive and easily searchable database," says Mandell.

Relevancy is issue

To use a physician's financial relationships as evidence, the plaintiff's attorney has to show the judge why the payment is relevant.

"I do not think that many judges will allow the payment alone to tar the doctor," says Robertson. However, if the plaintiff's attorney can tie the payment to the specific clinical decision that the physician made, then it might be admissible.

"Such a payment may show bias: that the physician erred on the side of prescribing, when he or she really should not have done so," says Robertson. A significant financial relationship could open up the physician to punitive damages, if the attorney can show an ulterior financial motive behind the prescribing decision.

"Physicians may be able to better defend such claims if they also make disclosures directly to patients, at the point when the patient is making

Executive Summary

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the ultimate treatment decision," says Robertson.

Financial motives to prescribe

Physicians with financial ties to drug and device companies might be more likely to prescribe those companies' products to their patients, says **Stephanie M. Godfrey**, JD, an attorney in the Philadelphia office of Pepper Hamilton.

"If physicians are overprescribing products or prescribing products that are not medically necessary for patients, the risk of patient harm and medical malpractice increases," she says.

The Sunshine Act database might reveal a financial tie to a company whose product is allegedly connected to the patient's injury. "A patient and his or her attorney may view the information as evidence that the physician's motivation to prescribe the product was based on financial considerations and not the best interests of the patient," says Godfrey. This situation is true even if a physician's prescribing habits are entirely appropriate and in accordance with accepted medical standards, she adds.

"Such information can be used to support a claim that the physician overprescribed products, or was negligent in prescribing products because of the financial incentives received from manufacturers," says Godfrey. She says physicians should do these things to protect themselves legally:

• Adhere to applicable state and federal disclosure requirements.

• Keep detailed documentation regarding the medical necessity of any products manufactured by companies with which the physician has a financial relationship.

• Consult with an attorney to make sure such arrangements comply with applicable healthcare laws, such as the federal Anti-Kickback Statute and Stark Law, and analogous state laws.

"To the extent such arrangements contain unlawful payments in exchange for referrals, physicians could also be prosecuted for violating fraud and abuse laws in addition to being sued for medical malpractice," warns Godfrey. ✦

Will apology cause patient to sue? Perception is 'outdated and inaccurate'

(Editor's Note: This is the second story in a two-part series on apology laws. This month, we report on how a physician's apology could affect the outcome of a malpractice suit. Last month, we covered a recent court ruling distinguishing between apologies that express sympathy and those that acknowledge fault.)

Evidence shows that "apology" laws "have done much more good than harm," says **Benjamin Ho**, PhD, assistant professor of economics at Vassar College in Poughkeepsie, NY. A 2011 analysis estimated that apologizing to a patient would reduce the average medical malpractice payout by $31,000.[1]

"States that passed such laws saw settlement speeds increase by 20%, especially in the most severe cases, where settlement amounts decreased by 14% to 17%," reports Ho, one of the study's authors.

The biggest predictor of whether a patient sues is the relationship between doctor and patient, according to Ho, "and apologies go a long way in restoring trust in that relationship." On the other hand, apologies also might alert the patient to the nature of the error. "Therefore, apologies could increase the likelihood the patient seeks legal counsel," acknowledges Ho.

The perception that an apology will cause a patient to sue is

CME OBJECTIVES

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- explain the impact of risk management issues on patients, physicians, legal counsel, and management;
- identify solutions to risk management problems for physicians, administrators, risk managers, and insurers to use in overcoming the challenges they face in daily practice.

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