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Health Law Strategist

Vigorous HIPAA Privacy Rule enforcement

By Nancy Brigner Waite

With the announcements of Cignet's $4.3 million civil monetary penalties and two recent resolution payments, HHS' Office of Civil Rights sent a clear message that it is serious about enforcement of HIPAA's Privacy Rule. Therefore, covered entities should ensure that they have a robust HIPAA compliance program including employee training, vigilant implementation of policies and procedures, internal audits and a prompt action plan to respond to incidents.

Background

The Health Insurance Portability and Accountability Act's (HIPAA's) Privacy Rule is a set of federal standards to protect the privacy of medical records and other health information maintained by covered entities. These standards provide patients with access to their medical records and with significant control over how their personal health information (PHI) is used and disclosed.

The U.S. Department of Health and Human Services (HHS) delegated Privacy Rule enforcement to HHS's Office of Civil Rights (OCR). For violations occurring before Feb. 18, 2009, OCR may impose civil monetary penalties (CMP) of up to $100 for each such violation. That penalty may not exceed $25,000 per year for multiple violations of the identical Privacy Rule requirement in a calendar year.

For violations of the Privacy Rule occurring on or after Feb. 18, 2009, consistent with the increased penalty provisions set forth in the Health Information Technology for Economic and Clinical Health (HITECH) Act, OCR is authorized to impose a range of CMP between $100 and $50,000 for each violation, provided the total amount imposed on a covered entity for violations of an identical requirement during a calendar year may not exceed $1.5 million.

OCR enforcement

As of May 31, 2011, OCR had investigated and resolved over 13,745 cases by requiring changes in privacy practices or other corrective actions by covered entities. Of the thousands of resolved cases, HHS has entered into six Resolution Agreements and recently issued its first CMP. A Resolution Agreement is a contract signed by HHS and a covered entity in which the covered entity agrees to perform certain obligations (e.g., staff

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training) and make reports to HHS, generally for a period of three years. During this period, HHS monitors the covered entity's compliance with its obligations. A Resolution Agreement likely also includes the payment of a resolution amount. These agreements are reserved to settle investigations with more serious outcomes. When HHS is not able to reach a satisfactory resolution through the covered entity's demonstrated compliance or corrective action through other informal means, CMP may be imposed for noncompliance.

First CMP issued by OCR

On Feb. 22, 2011, OCR announced that a covered entity, Cignet Health of Prince George's County, Maryland (Cignet), violated the Privacy Rule. OCR imposed a CMP of $4,351,600 for the violations, representing the first CMP issued by OCR for violations of the Privacy Rule. In its calculation, OCR utilized the increased penalty amounts authorized by the HITECH Act.

OCR found that Cignet violated 41 patients' rights by denying them access to their medical records. Each of these patients made a request to obtain their records between September 2008 and October 2009 and filed a complaint with OCR. The Privacy Rule requires that a covered entity provide patients with a copy of their medical records within 30 (and no later than 60) days of a patient request. The CMP for these violations was $1,351,600.

During OCR's investigations, Cignet refused to respond to OCR's repeated demands to produce the records. After OCR issued a subpoena and Cignet failed to respond to OCR, OCR filed a petition to enforce its subpoena and obtained a default judgment against Cignet on March 30, 2010. On April 7, 2010, Cignet delivered 59 boxes of medical records containing not only the medical records required by the subpoena but also the medical records of approximately 4500 individuals for whom OCR made no request and for whom Cignet had no basis for the disclosure of their PHI to OCR. With the exception of such delivery, Cignet made no efforts to resolve the complaints through informal means.

Covered entities are required under law to cooperate with OCR's investigations. OCR found that Cignet's failure to cooperate was due to willful neglect to comply with the Privacy Rule, and the CMP for these violations was $3 million.

Cignet's conduct with respect to the OCR investigation was extreme. However, the message is clear: covered entities should cooperate with the OCR when it is investigating a Privacy Rule complaint.

Recent resolution agreements

In a Resolution Agreement dated July 6, 2011, the University of California at Los Angeles Health System (UCLAHS) agreed to settle potential violations of the HIPAA Privacy and Security Rules for $865,000 and committed to a Corrective Action Plan (CAP). The Resolution Agreement resolved two separate complaints filed with OCR on behalf of two celebrity patients. The complaints alleged that UCLAHS employees repeatedly and impermissibly looked at these patients' electronic PHI. As part of its investigation, OCR found that from 2005-2008 unauthorized employees repeatedly looked at the electronic PHI of numerous other UCLAHS patients. The CAP requires UCLAHS to implement Privacy and Security policies and procedures approved by OCR, to conduct trainings for all UCLAHS employees who use PHI, to sanction employees who fail to comply with the policies and procedures, and to designate an independent monitor. In its press release related to this Resolution Agreement, OCR emphasized that "trainings and meaningful [HIPAA] policies and procedures, including audit trails, [must] become part of the every day operations of any health care provider."

On Feb. 14, 2011, OCR announced that General Hospital Corporation and Massachusetts General Physicians Organization Inc. (Mass General) signed a Resolution Agreement and agreed to pay $1 million to settle potential violations of the Privacy Rule. The facts that gave rise to the OCR investigation involved an employee of Mass General's Infectious Disease Associates outpatient practice, including patients with HIV/AIDS. In March 2009, the employee removed from Mass General premises documents

Editor's Notes

We publish *Health Law Strategist* to keep you informed of current legal developments in the health care industry. *Health Law Strategist* will provide you with practical information to assist in the management of your facility and help facilitate legal compliance.

Thank you for choosing *Health Law Strategist*. Please feel free to contact me if you wish to suggest topics for future issues.
Robert Cochran - 614.462.2248 or rcochran@szd.com

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Robert Cochran,
Editor

SZD.COM

COLUMBUS, OHIO
614.462.2700

CLEVELAND, OHIO
216.621.6501

containing PHI in order to work on the documents from home. The documents consisted of billing encounter forms containing the name, date of birth, medical record number, health insurer and policy number, diagnosis and name of provider of 66 patients and the practice's daily office schedules for three days containing the names and medical record numbers of 192 patients. While commuting to work, the employee left the documents on a subway train, and the documents were not recovered.

As part of the Resolution Agreement, Mass General agreed to enter into a CAP which requires it to:

- Develop and implement a comprehensive set of policies and procedures governing the physical removal and transport of PHI, laptop encryption and USB drive encryption;
- Train workforce members on these policies and procedures; and
- Monitor Mass General's compliance with the CAP and render semi-annual reports to HHS for a three-year period.

Comparison of Mass General to 2008 settlement

Mass General's $1 million resolution amount was higher than expected in light of the fact that the missing records were paper records, the number of patients was relatively small and this type of data breach is not unusual. For example, in 2008, OCR entered into its first Resolution Agreement with Providence Health & Services (Providence) to settle similar potential Privacy Rule violations.

On several occasions between September 2005 and March 2006, backup tapes, optical disks and laptops, all containing unencrypted electronic PHI, were removed from Providence premises and left unattended. The media and laptops were subsequently lost or stolen, compromising the PHI of over 386,000 patients. Under the Resolution Agreement, Providence paid a $100,000 resolution amount and implemented a Corrective Action Plan that required: revising its policies and procedures regarding physical and technical safeguards (e.g., encryption), governing off-site transport and storage of electronic media containing patient information, training workforce members on the safeguards, conducting audits and site visits of facilities, and submitting compliance reports to HHS for a period of three years.

Comparing the facts and the resolution payments between Providence and Mass General, it appears that OCR has become much more vigorous in Privacy Rule enforcement.

Conclusion

In the press release related to Mass General's settlement, OCR Director Georgina Verdugo stated, "[w]e hope the health care industry will take a close look at this [Resolution Agreement] and recognize that OCR is serious about HIPAA enforcement." Additionally, covered entities should expect continued robust enforcement as evidenced by OCR's request for a 13.6 percent increase in its budget for fiscal year 2012.

While Cignet's conduct was egregious, the magnitude of recent resolution amounts and the increased CMP available under the HITECH Act are a wake up call to covered entities to review their HIPAA compliance program. HIPAA compliance programs should include training for employees who have access to and use PHI, vigilant implementation of policies and procedures, regular internal audits and a prompt action plan to respond to incidents. In light of the fact that two of the five Resolution Agreements address off-site data breaches, covered entities should pay particular attention to their HIPAA policies and procedures related to transporting, storing or using PHI off-site.

For questions about HIPAA, contact Nancy Brigner Waite at 614.462.5015 or nwaite@szd.com or any member of SZD's Health Care Practice Group. ■

SZD Health Care Practice Group

Attorneys

Richard Barnhart	614.462.2246	rbarnhart@szd.com
Paul Bittner	614.462.2228	pbittner@szd.com
Robert Cochran	614.462.2248	rcochran@szd.com
Kris Dawley, Leader	614.462.2290	kdawley@szd.com
Asim Haque	614.462.1072	ahaque@szd.com
Stephen Kleinman	614.462.2287	skleinman@szd.com
Sue Porter	614.462.2314	sporter@szd.com
Nancy Brigner Waite	614.462.5015	nwaite@szd.com
Robert Weisman	614.462.2239	rweisman@szd.com
Hayley B. Williams	216.394.5070	hwilliams@szd.com

News and Notes

On Jan. 24, 2011, **Steve Kleinman** presented "Health Care Reform and its Implications for Skilled Nursing Facilities," at the Howard, Wershbale & Co. Health Fair.

On April 5, 2011, **Steve Kleinman** presented "Preparing for the Future: Health Care Reform and ACOs" at the Wexner Village Board Meeting.

On June 20, 2011, **Kris Dawley** presented "Wellness Programs: Overview of Legal Issues" at the AccBen University Wellness Conference held at Schottenstein Zox & Dunn.

Impact of Sunshine Law on physicians

By Nancy Brigner Waite

In response to growing concerns that physicians' financial relationships with pharmaceutical and medical device companies create inappropriate conflicts of interest in research and patient care, Section 6002 of the Patient Protection and Affordable Care Act implements the Physician Payments Sunshine Act (the Sunshine Act).

The Sunshine Act requires manufacturers of drugs, biological products, medical supplies and medical devices to annually report payments made to physicians or teaching hospitals to the Secretary of the Department of Health and Human Services (the Secretary). The Secretary must make the reported data publicly available. The expectation is that increased transparency will deter inappropriate conflicts of interest and will increase confidence that physicians are disseminating unbiased information.

By Oct. 1, 2011, the Centers for Medicare and Medicaid Services (CMS) will issue regulations including procedures for submitting information and for making reported information available to the public.

Highlights of the Sunshine Act

Required disclosures. By March 31, 2013, each "applicable manufacturer" that provides a payment or other transfer of value to a "covered recipient" during 2012 must report the payment or transfer of value to the Secretary. Subsequent annual reports must be submitted by the 90th day of each calendar year.

An "applicable manufacturer" is a manufacturer operating in the United States (or a U.S. territory, possession or commonwealth) that is engaged in the production or preparation of a drug, biological product, device or medical supply covered under Medicare, Medicaid or SCHIP.

A "covered recipient" is a physician or a teaching hospital. However, covered recipients do not include physicians who are employees of the applicable manufacturer.

Applicable manufacturers must submit the following information to the Secretary:

- Name and business address of the covered recipient and, in the case of a physician, the physician's specialty and National Provider Identifier (NPI).
- Amount of each payment.
- Date of each payment.
- Description of the form of payment.
- Nature of payment (e.g., consulting fees, compensation for services other than consulting, honoraria, gift, entertainment, food, travel, education, research, charitable contribution, royalty or license, ownership or investment interest, direct compensation for serving as a speaker for a medical education program or grant).
- If the payment or other transfer of value is related to marketing, education or research specific to a covered drug, device, biological or medical supply, the name of that item.
- Any other information the Secretary may require by regulation.

By Sept. 30, 2013, and on June 30 of each calendar year beginning thereafter, the Secretary will make the reported information available through a searchable website. However, the Act permits delayed publication for payments made pursuant to certain product research or development agreements and clinical investigations.

Ownership transparency. By March 31, 2013, and on the 90th day of each calendar year beginning thereafter, applicable manufacturers must submit to the Secretary certain information regarding any ownership or investment interest held by a physician (or an immediate family member of such physician) in the applicable manufacturer during the proceeding year.

Excluded transactions. The Sunshine Act exempts 13 types of transfers from its reporting requirements. For 2012, an applicable

manufacturer is not required to disclose a transfer of value which is less than $10, unless the aggregate amount transferred to the physician or teaching hospital during the calendar year exceeds $100. Annual increases to these thresholds will reflect increases to the consumer price index. Other exemptions include patient educational materials, in-kind items used for charity care, items provided under a warranty and dividends from publicly traded securities.

Penalties. Any applicable manufacturer that fails to submit required information will be subject to a civil monetary penalty ranging from $1,000 to $10,000 with annual penalties not to exceed $150,000. However, for knowingly failing to submit the required information, the applicable manufacturer is subject to a civil monetary penalty ranging from $10,000 to $100,000 with annual penalties not to exceed $1 million.

Pre-emption. The Sunshine Act only preempts state laws requiring an applicable manufacturer to disclose or report the type of information required to be disclosed under the Sunshine Act.

Impact on physicians

Interactions between physicians and industry are a fundamental component of translating research into innovative medical advances that improve patient care. However, these interactions are subject to increasing scrutiny because of their potential to influence physicians' medical judgment.

The Sunshine Act does not prohibit payments to physicians and teaching hospitals but is intended to provide greater transparency in their relationships with life science companies. The Act's transparency is consistent with a broad trend to increase transparency found in various state laws, institutional conflict of interest policies and industry codes of conduct.

Public disclosure of payments from applicable manufacturers is expected to have a significant impact on industry relationships with physicians.

- *Fuel for industry critics*. Physicians may become reluctant to participate in research and education activities when the physicians' fees are subject to public disclosure. Disclosure may subject the physicians to public scrutiny and media reports implying financial relationships with industry compromise physicians' medical independence. For example, in Massachusetts, pharmaceutical and medical device manufacturers must disclose certain financial transactions with health care providers. In November 2010, the disclosed information was first made publicly available. The next day, a Boston Globe article identified physicians who received payments and the amount and source of their payments and highlighted the physicians' malpractice histories, state licensure issues and professional conduct. The article also emphasized that "[p]ayments to physicians have come under scrutiny because of critics' concerns that the money influences doctors to prescribe newer and more expensive medications, helping to drive up the cost of health care."

- *Hospital reaction*. Health care institutions may react to the Sunshine Act by adopting internal policies that restrict physician interactions with life science companies. For example, leading academic medical centers have strengthened their conflict of interest policies to prohibit promotional speeches for pharmaceutical companies and to restrict outside pay for senior officials who sit on the board of pharmaceutical or biotechnology companies. These institutions fear that perceived conflicts of interest undermine the credibility not only of the individual who has the financial relationship, but also the institution the individual represents.

- *Anti-kickback/False claims data*. From a civil and criminal liability standpoint, the public disclosure of financial relationships will provide a new source of data to assist government enforcement officials in identifying payments that potentially violate state or federal anti-kickback statutes or induce false claims. Governmental officials will analyze the disclosed data to determine whether fees are illegal inducements to physicians for using or recommending manufacturers' products. Therefore, payments to physicians and teaching hospitals from applicable manufacturers must be for legitimate services and be consistent with fair market value of such services. Additionally, physicians should document that they actually provided the services for which they were paid.

- *Consistency with 1099*. Physicians must ensure that the publicly disclosed information matches the IRS Form 1099 that reports the value of the items or services physicians receive.

In conclusion, prior to Jan. 1, 2012 (when manufacturers must begin tracking payments under the Sunshine Act), physicians and teaching hospitals should carefully review their relationships with pharmaceutical, biological product, medical supply and medical device manufacturers to ensure that their payments from these industries can withstand scrutiny from the public and government enforcement agencies.

For questions about the Sunshine Law, contact Nancy Brigner Waite at 614.462.5015 or nwaite@szd.com or any member of SZD's Health Care Practice Group. ■

OIG advisory opinion allows hospital's complimentary transportation service

By Robert Cochran

On March 17, 2011, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued a favorable advisory opinion regarding a complimentary local transportation arrangement whereby a hospital would transport patients from physician offices located on (or contiguous to) the hospital's campus to the hospital if the patients require further treatment and cannot transport themselves. Although the proposed transportation arrangement potentially implicates the Anti-Kickback Statute and the civil monetary penalty (CMP) provisions of the Social Security Act, OIG concluded that it would not subject the hospital to administrative sanctions under the Anti-Kickback Statute or the CMP.

The hospital is a nonprofit, tax-exempt corporation that operates an acute care hospital and provides outpatient services. Under the proposed transportation arrangement, the hospital would provide complimentary local transportation to patients (and their families) that present at physician offices located on (or contiguous to) the hospital's campus, require further evaluation or treatment at the hospital's facility, and are unable to transport themselves. The usual distance a patient would be transported would be approximately one-fourth of a mile. The hospital has limited parking in close proximity to the hospital, limited public transportation options are available, and the campus walkways may be difficult for feeble or elderly patients to navigate. The hospital would not charge the passengers or any third-party payor for the transportation, nor would it claim the costs of the transportation directly or indirectly on any federal health care program cost report or claim, or otherwise shift the costs of the transportation arrangement to any federal health care program. The service would be offered uniformly to all patients regardless of income or source of payment for the hospital's services.

OIG acknowledged that the proposed arrangement implicates both the Anti-Kickback Statute and CMP for inducements to beneficiaries because the transportation could be offered to induce federal health care program beneficiaries to obtain federally payable items or services from the hospital. Moreover, the transportation could be of more than nominal value because it could exceed $10 per transport or $50 on an annual basis. Nonetheless, OIG concluded that it would not subject the hospital to administrative sanctions under the Anti-Kickback Statute or the CMP. The OIG based this conclusion on the following:

1. The proposed arrangement would not selectively limit eligibility to targeted populations of federal health care program beneficiaries. Instead, it would be offered uniformly to all patients.

2. The transportation provided under the proposed arrangement would be reasonable. For example, the proposed arrangement would not offer expensive transportation such as limousines.

3. The transportation would be offered locally from physician offices located on or contiguous to the hospital and would be approximately one-fourth of a mile.

4. Although the hospital would inform its physicians about the availability of the complimentary transportation, the hospital would not advertise the arrangement.

5. The hospital certified that the availability of local public transportation and parking is limited.

6. Finally, the cost of the transportation would neither be claimed on any federal health care program cost report or claim, nor otherwise shifted to any federal health care program.

For questions about federal fraud and abuse laws, contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group. ■

Federal District Court *dismisses case against* former drug company lawyer

By Robert Cochran

On May 10, 2011, a federal district court judge issued a surprise ruling dismissing a criminal case against a former in-house lawyer for GlaxoSmithKline (GSK). The decision is significant for health care lawyers and their clients because it reaffirms the importance of the attorney-client privilege, which many in the corporate defense bar thought was under attack as a result of the government's case.

The lawyer, Laura Stevens, was indicted in 2010 on charges of obstruction of justice and making false statements. The charges related to an FDA investigation into GSK's promotion of Wellbutrin for off-label uses. The government alleged that Stevens withheld materials responsive to the FDA's inquiry, represented to FDA that GSK's response was complete when it was not, and that she sent a series of correspondence to FDA in which she concealed incriminating evidence of the extent of GSK's promotion of Wellbutrin for off-label uses.

In a relatively rare move, the court dismissed the indictment against Stevens at trial after the government had finished presenting its case to the jury. In dismissing the case, the court emphasized the importance of the attorney-client privilege. The court found fault with an earlier ruling by a magistrate judge, which compelled the production of documents containing privileged attorney-client material. The Court found that the case was not an instance of an attorney appointed to help a client commit a crime, but instead showed a "studied," "thoughtful" and "good faith effort" by Stevens to gather information and act on behalf of her client, GSK. As a result, the court concluded the government should never have received access to the privileged information in the first place.

The court also noted that while some of Stevens' responses to the FDA may not have been perfect or may not have satisfied FDA, they were sent to the FDA in the course of her bona fide legal representation of a client and in good faith reliance on both outside counsel and in-house lawyers for GSK. The court noted that Stevens sought and obtained the advice and counsel of numerous lawyers. She made full disclosure to them. Every decision that she made and every letter that she wrote was done by consensus. The court concluded that even if some of the statements were not literally true, it is clear that they were made in good faith.

The court stressed the serious implications that may arise from this action and the possibility of abuse in permitting prosecution of a lawyer for providing legal guidance. The Judge made it clear that while lawyers "do not get a free pass to commit crimes," they "should never fear prosecution because of advice that he or she has given to a client who consults him or her." The court stressed that "vigorously and zealously representing a client is no basis for charging a lawyer with obstruction of justice."

Moreover, the Court asserted that the importance of the confidential nature of the communication between the attorney and client can not be overlooked, and "a client should never fear that its confidences will be divulged unless its purpose in consulting the lawyer was for the purpose of committing a crime or a fraud." The court concluded that Stevens should never have been prosecuted and should be permitted to resume her career.

The decision highlights the importance of the attorney-client privilege, as well as the importance of full disclosure of information between lawyers and their clients.

For questions about attorney-client privilege, contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group. ■

Ohio's apology statute: Sorry seems to be the hardest word

By Stephen Kleinman

In a ruling that is extremely unfavorable to physicians, the Ohio Ninth District Court of Appeals recently held that Ohio's apology statute protects expressions of sympathy but does not protect statements admitting liability in a malpractice case.

Historically, medical schools have trained physicians to not say "I'm sorry" after a medical error. Based upon malpractice liability concerns, this training is often reinforced by defense attorneys. However, studies have shown that patients and their families are less likely to sue if they receive an appropriate apology. To encourage physicians to show compassion after a medical error, many states have adopted laws protecting apologies.

Under Ohio's apology statute, RC §2317.43, in a civil action brought by an alleged victim of medical malpractice, a health care provider's statements expressing apology are inadmissible. In *Davis v. Wooster Orthopaedics & Sports Medicine, Inc.*, 2011-Ohio-3199 (June 29, 2011), the Ohio Ninth District Court of Appeals held that Ohio's apology statute protects only expressions of sympathy and not admissions of fault.

R.C. 2317.43

(A) In any civil action brought by an alleged victim of an unanticipated outcome of medical care or in any arbitration proceeding related to such a civil action, any and all statements, affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence that are made by a health care provider or an employee of a health care provider to the alleged victim, a relative of the alleged victim, or a representative of the alleged victim, and that relate to the discomfort, pain, suffering, injury, or death of the alleged victim as the result of the unanticipated outcome of medical care are inadmissible as evidence of an admission of liability or as evidence of an admission against interest.

(B) For purposes of this section, unless the context otherwise requires:

(1) "Health care provider" has the same meaning as in division (B)(5) of section 2317.02 of the Revised Code.

(2) "Relative" means a victim's spouse, parent, grandparent, stepfather, stepmother, child, grandchild, brother, sister, half brother, half sister, or spouse's parents. The term includes said relationships that are created as a result of adoption. In addition, "relative" includes any person who has a family-type relationship with a victim.

(3) "Representative" means a legal guardian, attorney, person designated to make decisions on behalf of a patient under a medical power of attorney, or any person recognized in law or custom as a patient's agent.

(4) "Unanticipated outcome" means the outcome of a medical treatment or procedure that differs from an expected result.

Davis v. Wooster Orthopaedics & Sports Medicine, Inc.

This case involved Barbara Davis who was 49 years old when she died following back surgery on July 23, 2004. Her husband filed a wrongful death action against her orthopaedic surgeon, Dr. Michael Knapic, and his practice group. Mr. Davis alleged that Dr. Knapic negligently performed a lumbar microdiscetomy by completely severing Mrs. Davis's left common iliac artery and lacerating her iliac vein during the procedure and failing to timely diagnose and treat the medical condition that arose. At trial, Mr. Davis and his daughter testified that, after the surgery, Dr. Knapic told them he had nicked an artery and took full responsibility for it. The jury awarded a $3 million verdict.

On appeal, Dr. Knapic argued that the word "apology," as used in the Ohio's apology statute, was intended to include an acknowledgement of fault in addition to an expression of sympathy. After reviewing various states' apology laws and the Ohio statute's legislative history, the court concluded the intent was to protect pure expressions of apology but not admission of fault.

The appellate court held the trial court had properly admitted the testimony of Mr. Davis and his daughter regarding Dr. Knapic's admission of fault. The $3 million verdict was upheld.

Conclusion

Physicians in Ohio must exercise extreme caution regarding making any statements to patients or family members related to a medical error. The appellate court's narrow interpretation of Ohio's apology statute essentially limits protected apologies to "I'm sorry for your loss." If physicians in Ohio give a full apology in which they express sympathy and accept fault, the admission of fault is admissible in evidence in any subsequent malpractice lawsuit.

For questions about the apology statute, contact Steve Kleinman at 614.462.2287 or skleinman@szd.com or any member of SZD's Health Care Practice Group. ■