



# **Newsletters**

# **Medical Litigation Newsletter - August 2013**

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Medical Litigation Newsletter

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# I'm Sorry Laws: A Multistate Analysis

There is anecdotal evidence and a number of studies suggesting that improvements in bedside manner and development of communication skills can play a role in preventing litigation against health care providers. Tension exists, however, regarding communications with patients and family members after an unexpected result and the possibility that such discussions could be used against the care provider in some later legal proceeding.

Post-occurrence communications are being expected of care providers as accreditation organizations and medical associations are making recommendations and applying criteria requiring communication of "adverse events" or "unanticipated outcomes." In this environment of uncertainty, apprehension, and mutual suspicion between provider and patient, many states have enacted "I'm Sorry" statutes in an attempt to encourage transparency and communication while reducing the fear of making some statement that could later be viewed as evidence of medical malpractice. This article is a general discussion of "I'm Sorry" laws and some potential benefits and pitfalls that they create.

The Admission Against Interest

It should come as no surprise that, if litigation has reached the point of trial before a jury, the defendant will be contending one or more of the following:

- That the defendant is not guilty of negligence;
- That any alleged negligent conduct did not cause the damages claimed by the plaintiff; or
- That the plaintiff is not injured to the extent claimed.

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In a medical malpractice context, these arguments will be supported by the opinion testimony of one or more of the defendants and by one or more of the defendants' experts.

Insofar as the health care provider has made any oral or written statement inconsistent with any or all of the above contentions, the statements may be considered "admissions," "admissions against interest," or "prior inconsistent statements." Such statements may be admissible at the time of trial as evidence of a fact or opinion held by the party making the prior inconsistent statement and in conflict with the position taken during the course of the judicial proceeding.

The impact of such a prior inconsistent statement upon a jury's deliberations depends in no small part upon the circumstances of the statement and the opposing party's ability to prove that the prior inconsistent statement was made. With adequate proof, however, the importance of such evidence cannot not be overstated. In a medical malpractice setting, a statement by a care provider made close to the time of the occurrence at issue and at a time before the speaker was placed under the pressure of pending litigation can have significant impact upon the deliberation of the jury.

Defense attorneys generally advise that providers stay away from apologetic language due to concern that such may be deemed "admissions" contrary to positions taken at trial. Such restraints in communication, however, have been argued as causing offense, which gives rise to the desire to pursue a medical malpractice action. This early silence is the subject matter of the "I'm Sorry" laws.

Communication Between Care Provider and Patient — Does It Make a Difference?

"I'm Sorry" laws are intended to foster better communication between health care providers and patients. As a perceived additional benefit, there is the belief that quality communication between provider and patient can prevent the pursuit of medical malpractice litigation. Several studies attempting to establish such links have been published. Certainly any attorney who has spent time representing health care providers in medical malpractice litigation can provide anecdotal evidence suggesting a link.

Attorneys who routinely represent medical malpractice defendants can provide examples of patients or family members who have been offended by health care providers' poor communication skills. Many witnesses speak to a lack of response to questions or comments once an unanticipated event or an adverse result has occurred. Patients, or their family members, feel that the silence proves a lack of concern and a withholding of information during a critical time in the course of the patient's care.

Studies suggest that of the significant number of adverse events caused by medical negligence, only a small percentage of the patients and families harmed by medical negligence file malpractice lawsuits. What prevents a patient, or a patient's family, from pursuing a lawsuit after there has been injury as a result of medical negligence? Some literature suggests that the nature of the communication between provider and patient plays a role.

In a 1997 study, Dr. Wendy Levinson published her findings after analysis of communication between patients and physicians. Levinson, W.; Roter, D.; Mulloole, J., *et al.*: "Physician Patient Communication: The Relationship with Malpractice Claims Among Primary Care Physicians and Surgeons." *JAMA* 1997; 277: 553-559. What Dr. Levinson reported was that, at least with primary care physicians, there were significant differences noted in the communication practices of physicians who had malpractice claims brought against them and those who had not. She found that those physicians who spent more time in routine visits, engaged in more interaction with their patients, and provided more education to patients were sued less than those who did not engage in such practices.

But would an apology or an admission of fault *after* an unexpected result has occurred reduce the likelihood of litigation? It may well be that a physician who is likely to express condolences for an unanticipated outcome is one who would have, for the entirety of the course of care, been engaged in good communication and therefore less likely to be sued in any event. It also stands to reason that the extent of the injury plays a critical role in whether or not a lawsuit is filed. It is also likely true that the ability of the patient or his or her family to sustain the financial and emotional impact of an unanticipated event makes a difference.

Standards Directing Disclosure of "Unanticipated Outcomes"



Credentialing entities and medical associations are moving toward transparency and communication of unanticipated outcomes to patients. The latest accreditation manual published by the Joint Commission — A Comprehensive Accreditation Manual For Hospitals; the Joint Commission: CAMH Update 1, March 2013 — has published standards for hospitals under the subsection regarding the patient's right to participate in decisions about his or her care, treatment and services. One element for performance under the standard requires hospitals to inform the patient or surrogate decision maker about unanticipated outcomes of care, treatment and services. The same section includes an element requiring a licensed independent practitioner to advise the patient about unanticipated outcomes.

The current Joint Commission standard links the above requirements to "sentinel events." The manual defines a "sentinel event" as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof." Thus, it could be argued that the Joint Commission standard mandates disclosure not only of unanticipated outcomes, but unanticipated outcomes that were possible under the circumstances.

In "AMA Counsel on Ethical and Judicial Affairs: Code of Ethics," *Annotated Current Opinions*, 2010-2011, the American Medical Association (AMA) discusses the disclosure of significant medical complications to patients. In Section 8.12 of the AMA Code of Medical Ethics the standard states that a physician is "ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred." This includes those facts of significant complications resulting from mistake or judgment. Thus, the AMA standard seems to require the physician to go so far as to identify and disclose what he or she perceives to have been a mistake. This is no simple matter, however, in the aftermath of what may be a recognized complication, a systemic failure, or a course of care that may have included a "mistake" that in no way caused or contributed to cause injury to the patient.

Of course, disclosure of an "unanticipated outcome" or a "significant complication" is different than an apology or an expression of condolences for an unwanted outcome. One can express a simple statement of fact indicating that an event has occurred without apologizing for an event and without admitting negligence or placing fault on a care provider.

In conjunction with the trend toward encouraging transparency, states have begun enacting "I'm Sorry" laws in an attempt to facilitate communication and alleviate the provider's concern about the use of an apology as an admission should the matter go to trial. We are early in the development of case law interpreting such laws and the ambiguous nature of some of the statutes themselves creates concern over what language will be protected.

#### "I'm Sorry" Laws

Using public policy reasons to enact laws prohibiting evidence of statements that might otherwise be construed to be admissions is not a new idea. To promote resolution, evidence of settlement discussions are generally inadmissible. Illinois has a statute stating that the providing of payment for medical bills shall in no way be construed to be evidence of an admission of fault at trial. 735 ILCS 5/8-1901. Indeed, it is to this statutory section that Illinois added its "I'm Sorry" Law in 2005. While there is a trend to enact "I'm Sorry" laws, very little case law addresses the issues raised by such statutes.

A majority of states have enacted some form of an "I'm Sorry" law. The communication protected by such laws, however, differs from state to state. Most states have enacted "I'm Sorry" laws that bar the admissibility of statements, writings or gestures expressing apology, sympathy, compassion, condolences, commiseration or a general sense of benevolence. A statement of fault, however, is not barred from trial in those jurisdictions. Some of the states with this type of statute include California, Delaware, Florida and Michigan.

When does an expression of condolences or an apology cross the line and become an admission of fault? Language is complicated and a statement made in a time of stress can be understood by two different listeners in two different ways. One person hearing an apology, perhaps expressed in words beyond a simple "I'm Sorry," may understand that statement as an acceptance of fault. A different person, standing in the same room, may understand that same statement as nothing more than an expression of sympathy for some undesirable outcome.

The Ninth District Court of Appeals of Ohio considered some of the inaccuracies of language in addressing the Ohio "I'm Sorry" law in 2011. *Davis v. Wooster Orthopaedics & Sports Med., Inc.*, 193 Ohio App. 3d 581, 952 N.E.2d 1216. Ohio has an apology statute providing that all statements expressing "apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence" are inadmissible as evidence at time of trial. Ohio Rev. Code § 2317.43. The *Davis* 



court considered whether defendant physician's statement could be construed to be an admission of fault not subject to the protection of the statute.

In *Davis*, the surgeon approached the family after performing back surgery and allegedly told them that he had nicked an artery. The trial court allowed the husband and daughter to testify as to the surgeon's conversations with them during which the surgeon stated, "it's my fault. I take full responsibility. In my five years I have never had anything like this happen." The appellate court affirmed the trial court's decision to allow that testimony to be presented to the jury.

In 2013 the Supreme Court of Ohio considered a case involving a physician who apparently stopped just short of accepting fault for a patient's injury. *The Estate of Johnson v. Randall Smith*, 2013 WL 1760949 (Ohio). In *Johnson*, plaintiff patient suffered from a complication due to bile duct injury occurring during gallbladder surgery. Defendant physician, after the complication, told the patient, "I take full responsibility for this. Everything will be okay." The Court referred to the trial court's finding that the physician was faced with a distressed patient who was upset and that the physician made a statement "designed to comfort his patient." According to the Court, that was "precisely the type of evidence" that the Ohio Apology Statute was designed to exclude as evidence of liability.

As long as we communicate, there will be failures in communication. Difficulties will arise in attempting to interpret the difference between an acceptance of fault and an expression of condolences. Additional difficulties appear likely when a court attempts to consider a physician's motivations in making a statement. Is a statement made accepting blame and responsibility, or is it made in the context of comforting a distressed patient? Such motivations appear to have played an important role in this decision rendered by the Ohio Supreme Court.

A minority of states have enacted "I'm Sorry" laws wherein no distinction is made between an expression of sympathy and an expression of fault. In these jurisdictions even a statement of fault made after an unanticipated result is excluded from evidence in a subsequent medical malpractice action. This type of "I'm Sorry" law seems to be a reflection of the complexities of both communication and medical malpractice litigation. Statements of fault or blame made shortly after an occurrence are prone to inaccuracy as they may be based upon a less than complete understanding of the circumstances impacting the true cause. States with statutes excluding such statements of fault as evidence include Montana, North Dakota and Oklahoma.

Illinois had previously enacted its own "I'm Sorry" Law under Public Act 94-677 (2005), with an effective date of August 25, 2005. Under this act, three criteria were analyzed to determine whether an apology would be inadmissible against a health care provider in the legal setting. First, the statement made by the medical provider had to be "any expression of grief, apology or explanation." In addition, the statement had to have been made by a health care provider defined as a "hospital, nursing home, an employee or agent thereof, a physician or another licensed health care professional." Third, the apology must have been made to a patient, the patient's family or the patient's legal representative within 72 hours of when the provider knew, or should have known, of the potential cause of the adverse event. If all three criteria were met, then the apology was deemed inadmissible as evidence in court or before "any tribunal, board, agency or person." Public Act 94-677 was held unconstitutional in *Lebron v. Gottlieb Memorial Hospital*, 237 III. 2d 217, 930 N.E.2d 895 (2010). Because the different provisions enacted by Public Act 94-677 could not be severed, the Illinois "I'm Sorry" law became void.

An attempt is currently underway in Illinois to reenact certain sections of Public Act 94-677. On February 15, 2013, a new bill was proposed by Illinois Senator Jason A. Barickman to the Illinois 98th General Assembly during its First Regular Session. With regard to the Illinois "I'm Sorry" law, this new bill is virtually identical to what had previously been enacted. At the time of this writing Illinois Senate Bill No. 2160 was still in committee.

The Illinois statute adds "explanation" to the list of the types of communications protected from being admissible at time of trial. It also states that to be protected the communication must be made within 72 hours of obtaining knowledge of the "cause" of the adverse event. While the language is vague, it seems to contemplate protection of a provider's "explanation" of the "cause" of an outcome. Some may construe such communication as including a discussion of "fault."

This vague language provides little comfort to the provider communicating with the patient after an occurrence. The discomfort is not alleviated by the language at the end of the provision which warns that "nothing in this section precludes the discovery or the admissibility of any other facts regarding the patient's treatment or outcomes otherwise permitted by



law." As we know from the discussion above, admissions against interest are generally admissible at time of trial.

Given the vague language and the lack of case law explaining how this statute is to be applied, it is understandable that a provider would continue to take great caution in providing any sort of explanation of cause for an inadequate or unanticipated outcome. While it appears that an expression of remorse and the specifically described "apology" would be inadmissible, any communication consisting of more than that seems to fall into a grey area under this statutory section.

It must be remembered that this statute has yet to be become law. Illinois is currently without an "I'm Sorry" law and even expressions of condolences or apologies may not be protected communications at the present time.

#### Conclusion

Notwithstanding what may be commendable efforts of a state's legislature, the inaccuracies of language and the difficulty of communicating accurately and effectively after an adverse event will continue to concern care providers. While "I'm Sorry" laws are an attempt to facilitate communication between provider and patient, there is no legislature or attorney that can "script" a conversation between a provider and patient in the stressful and difficult times following an unanticipated or adverse result. Hinshaw & Culbertson LLP has attorneys in a number of jurisdictions across the United States who can provide guidance concerning the laws in effect in a jurisdiction of interest.

# Fewer Than 90 Days and Counting . . . Are You Ready for the HIPAA Compliance Deadline?

Covered entities and business associates have fewer than 90 days, or until September 23, 2013, to come into full compliance with the HIPAA Omnibus Final Rule (the "HIPAA Final Rule"). The HIPAA Final Rule details several new requirements for covered entities and business associates and requires changes in policies and procedures of covered entities and business associates. It expands the definition of "business associate" to vendors and subcontractors who may not even be aware they are covered by HIPAA; makes business associates directly responsible for keeping data safe and secure; and expands criminal and civil penalties for covered entities and business associates who violate HIPAA.

Compliance with these new requirements will require substantial time and effort. Covered entities and business associates only have a short time to bring themselves into compliance with the mandatory changes required by the HIPAA Final Rule. It is essential that policies and procedures, forms and agreements reflect both the HIPAA Final Rule's requirements and the covered entity or business associate's actual practices. Significant fines may be imposed for failure to comply with internal process and practice. Compliance with the HIPAA Final Rule is mandatory. The potential consequences for violations are severe and include civil monetary penalties as well as criminal penalties.

Covered entities and business associates should immediately begin to address the action items below. Note, these are only examples and are not a complete list of changes required by the Final Rule.

For Covered Entities (Providers, Facilities, Health Systems, Clearinghouses and Group Health Plans)

#### Business Associate Agreements

- Update your business associate agreement templates to comply with the HIPAA Final Rule.
- Identify each business associate you deal with to ensure that you have a current, signed, up-to-date business associate agreement that complies with the HIPAA Final Rule.
- Inventory each of your vendors and subcontractors who have access to, use, disclose or create protected health information (PHI) to determine if they are business associates.
- Ensure that you have current, signed, up-to-date business associate agreements with any vendors or subcontractors who have access to, use, or disclose PHI on your behalf.
- Be aware that the definition of "business associate" has been expanded and that vendors and subcontractors (including accountable care organizations, accountants, attorneys, consultants, technology vendors and other service-related vendors) may not be aware that they are now a business associate and have new legal obligations to protect the privacy and security of PHI and to develop and implement HIPAA training, policies and procedures.



- Develop and implement a strategy for amending/renegotiating existing business associate agreements so that up-todate signed agreements that comply with the HIPAA Final Rule are in place no later than September 23, 2013.
- Develop policies and procedures to address new subcontractor requirements.
- Develop policies and procedures for monitoring business associate HIPAA compliance.
- Develop policies and procedures to ensure that as you add vendors or subcontractors you determine whether a business associate agreement is necessary.

#### Patient Rights

- Review and modify HIPAA policies and procedures to address new requirements for protecting psychotherapy notes.
- Review and modify HIPAA policies and procedures concerning marketing, fundraising and restrictions on the sale of PHI
- Review and modify HIPAA policies and procedures on research, decedents, student immunization records, and use of genetic information in underwriting.
- Review and revise HIPAA policies and procedures concerning notices of breaches, right to restrict disclosures, to access electronic PHI, and to designate third parties who may receive PHI.
- Update forms to reflect changes required by the HIPAA Final Rule.

#### Notice of Privacy Practices

- Update your notice of privacy practices to comply with the HIPAA Final Rule.
- Establish and implement a mechanism for distributing your revised notice of privacy practices.

#### Marketing, Fundraising and Sale of PHI

- Determine whether your organization uses PHI to promote a product or service, and if so, whether you need to obtain an authorization.
- Review and modify existing HIPAA policies and procedures and forms to address new marketing requirements.
- Review and modify your fundraising policies and procedures to comply with the HIPAA Final Rule, including developing
  a database for fundraising that allows recipients to opt out and not receive fundraising communications.
- Review your business operations to determine if you are selling PHI and if so, whether you are using authorizations
  that comply with the HIPAA Final Rule.

#### Research

Review your research activities and your authorizations to ensure that they comply with the HIPAA Final Rule.

#### Breach Notification

- Develop, implement and document processes for conducting risk assessment to determine the probability of compromise of PHI in the event of a breach of unsecured PHI.
- Develop and implement a breach response/security incident reporting program.
- Develop a notification process in the event of a breach, and integrate state breach notification requirements with HIPAA breach notification requirements.

#### Workforce Education and Training

- Train workforce members on their new privacy, security, risk assessment and breach notification responsibilities and on the new policies, procedures and forms. Workforce members should be trained to identify and report breaches of unsecured PHI in a timely manner.
- Integrate training and compliance into workforce evaluation and disciplinary procedures.



- Ensure that your workforce is trained on compliance with the new business associate requirements.
- Ensure that training is documented and that you have mechanisms in place for auditing and ensuring workforce compliance.

#### For Business Associates and Subcontractors

Familiarize yourself with the requirements for business associates under the HIPAA Final Rule, recognizing that business associates who have access to PHI are directly liable for compliance with the HIPAA privacy and security rules and are subject to civil fines and criminal penalties for violations.

#### Business Associate Agreements

- Update your business associate agreement templates to comply with the HIPAA Final Rule.
- Ensure that you have signed up-to-date business associate agreements with all covered entities.
- Evaluate your relationship with vendors and subcontractors and determine if they are business associates.
- Ensure that you have signed-up-to-date business associate agreements with all subcontractors or vendors who have access to, use, or disclose PHI on your behalf.

#### Privacy Rule Requirements

• Ensure that you have policies and procedures required by the privacy rule concerning the use, disclosure and protection of PHI as required by the privacy rule for business associates.

#### Security Rule Requirements

- Designate a security official.
- Perform a risk assessment of your information security processes and procedures and establish reasonable safeguards to ensure that PHI is secure and not subject to intentional or inadvertent breaches.
- Implement appropriate administrative, physical and technical safeguards to address vulnerabilities identified in your risk assessment.
- Develop and implement policies, procedures and forms addressing security obligations for PHI.
- Develop policies and procedures to monitor subcontractor business associate compliance with HIPAA.

#### Breach Notification

- Develop and implement processes to discover breaches of unsecured PHI.
- Develop and implement a process to conduct and document risk assessments for determining the probability of compromise of PHI in the event of a breach.
- Develop and implement a breach response/security incident reporting program.
- Develop a notification process in the event of a breach, and integrate state breach notification requirements with HIPAA breach notification requirements.

#### Workforce Education and Training

- Train relevant workforce members on their revised privacy, security and breach notification policies. Workforce members should be trained to timely identify and report breaches of unsecured PHI.
- Ensure that training is documented and that you have mechanisms in place for auditing and ensuring workforce compliance.



## How We Can Help

Hinshaw & Culbertson LLP attorneys have extensive experience developing and advising on privacy and information security programs. If you have questions or need assistance in determining how to make the requisite changes to your policies, procedures, and practices in order to come into compliance with the Final Rule, please call Michael A. Dowell or your regular Hinshaw attorney.

### Hinshaw Representative Matters

Paul Estes and Jesse Placher represented a general surgeon who was sued, along with his partner, for failure to timely diagnose a post-operative bowel perforation. Plaintiffs were a patient and her husband. The care and treatment at issue took place in July 2005, when the patient was approximately 49 years old. She had about three years of abdominal pain posthysterectomy. The co-defendant performed a laporoscopic lysis of adhesions on July 13, 2005. On July 17, 2005, the husband took the patient to the emergency room with complaints of fever, pain, vomiting nine times, and no bowel movements since the surgery. She was admitted with a diagnosis of ileus versus bowel obstruction. A CT scan was ordered the following morning and did not reveal a bowel perforation. It was determined that the patient did have an abscess. An interventional radiology consult was ordered and it was agreed to treat the abscess conservatively via a drain. On July 21, the patient was deteriorating and sent to the intensive care unit. On July 22, another CT was taken and revealed a perforation. An operation was performed by the co-defendant immediately thereafter. As a result of her undiagnosed bowel perforation, she developed sepsis and ultimately underwent number of additional procedures and several months of physical therapy and home health assistance. In the patient's lawsuit, the surgeon was named because he had followed the patient in the hospital between July 18-22. The surgeon was dismissed from the case, with prejudice, on the third day of trial, and the matter proceeded to verdict against the co-defendant. A verdict was subsequently returned in favor of the codefendant.

#### Case Updates

The Indiana Court of Appeals affirmed a summary judgment victory that Patrick Devine, obtained on behalf of defendant pain management physician. In this case, Laskowski v. Kazi, first reported on in the July 2, 2012, issue of the Medical Litigation Newsletter, the physician was accused of having negligently performed a cervical epidural steroid injection. In Indiana, a medical malpractice claim must be submitted to a medical review panel composed of three physicians before it can be filed in court. The physician prevailed before the panel, and plaintiff refiled the case in Indiana state court. The physician moved for summary judgment, based upon the favorable panel opinion. Plaintiff filed an affidavit by New York physician, asserting that defendant physician had breached the standard of care in his procedure. The court struck the affidavit, finding that the affiant's deposition testimony demonstrated that his opinions were based upon inferential speculation. The court then granted summary judgment for defendant physician.

Devine is also representing a family practice physician in Chaffins v. Kauffman, et al., which was first reported on in the June 10, 2013, issue of the Medical Litigation Newsletter. In this case, plaintiff patient alleged negligence due to a bowel perforation during a colonoscopy. The patient complained of pain following the physician's procedure, but was sent home by hospital staff. The patient remained at home for approximately 12 hours before contacting the physician, who suggested that she return to the hospital where the perforation was discovered. The patient required a colostomy and reversal. Pursuant to Indiana law, the matter proceeded to a medical review panel consisting of three physicians, who reviewed the parties' written submissions and rendered a unanimous, favorable opinion for the physician. As legally permitted, the patient refiled her case in state court. Hinshaw moved for summary judgment on the physician's behalf based upon the panel opinion and the requirement that the patient prove her case through expert testimony. Two days before the hearing on summary judgment, the patient filed a response, including an expert affidavit from a gastroenterologist implicating negligence on the part of the physician. Hinshaw requested and obtained leave to depose the patient's expert prior to filing a summary judgment reply. At the expert's deposition, Hinshaw exposed the fact that the expert's opinions of negligence were based solely upon speculation. Thereafter, Hinshaw filed a reply on the physician's behalf and argued that the opinions of the patient's expert were unreliable and could not create an issue of material fact. The court agreed and granted summary judgment in favor of the physician. An appeal followed, and oral argument will be broadcast live over the internet from the Indiana Court of Appeals website on August 27, at 10:00 a.m. Eastern.



#### Download or read the complete newsletter here: Medical Litigation Newsletter - August 2013

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# Webinar Series: The HIPAA Omnibus Final Rule and Impending Compliance Deadlines: Are You Ready?

Hinshaw recently presented a webinar miniseries on issues relating to the HIPAA Omnibus Final Rule. Health care providers and business associates alike benefited from these programs that focused on specific challenges posed by the Final Rule. These complimentary webinars were designed to identify issues for providers and business associates, and provided tools and action items that attendees can apply to their own circumstances to help them achieve their compliance objectives. The topics and presenters were:

General Changes to Privacy Practices - Wednesday, July 31, 2013

Business Associate Agreements and Business Associate Requirements - Wednesday, August 7, 2013

Presenter: Lora Zimmer

Breach, Breach Notification, and Changes in Enforcement Activities - Wednesday, August 14, 2013

Presenters: Roy Bossen and Michael Dowell

The recorded webinars will be available for replay on Hinshaw's website. Please note, CLE is not available for webinar replays, only attendance at the live program.