

BB REVIEW

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Healthcare News

March 2008

PATIENT SAFETY / LIABILITY

HHS Publishes Long-Awaited Proposed rule on Collection of Patient Safety Data

On February 11 the Department of Health and Human Services ("HHS") released a long-awaited proposed rule establishing a process in which health care providers *can* report medical errors voluntarily. The proposed rule also grants privilege protection for patient safety information making it generally not subject to subpoena, discovery or disclosure in disciplinary proceedings against a physician or healthcare practitioner, as well as inadmissible in civil or criminal proceedings.

Patient safety organizations ("PSOs") will be established to collect and analyze medical data, and the aggregation of that information will be used to uncover trends in patient treatment that would help lower the incidence of medical errors.

According to the proposed rule, providers, which in many cases already are collecting this data, could provide data to the PSOs subject to confidentiality and privilege protectors.

Although well-intended, the proposed rule fails to adequately protect providers that share information from potential liability. Although the proposed rule generally protects information disclosed to PSOs, the federal protection is not extended to information other than the precise reports collected for and made to the PSO.

HHS's Office for Civil Rights will regulate and enforce any breaches of confidentiality of patient information, which will be subject to civil monetary penalties of up to \$20,000 per act. Providers participating in the effort also will be expected to comply with privacy standards established under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

HHS said it expected about one hundred (100) PSOs to be operational three years after enactment of a final proposed rule.

The Patient Safety Act was enacted as a result of a 1999 Institute of Medicine Report ("IOM") report that found at least 44,000, and as many as 98,000, individuals die in U.S. hospitals annually as a result of preventable medical errors, according to HHS.

HHS said the proposed rule does not require providers to participate in the program, but "many providers will do so in order to take full advantage of the protections of the Patient Safety Act."

Life Sentence for Osteopath in Painkiller Drug Deaths Upheld by Eleventh Circuit

A conviction and resulting life sentence of a Florida osteopath for wire fraud, health care fraud, and illegally prescribing narcotics was recently upheld by the federal appeals court for Alabama, Florida and Georgia. This fraud was implicated in the deaths of five patients. *United States v. Merrill*, No. 06-14076 (11th Cir., Jan. 17, 2008).

Further, the Eleventh Circuit rejected Merrill's contention that the district court abused its discretion when it allowed the government to introduce as evidence a chart summarizing more than 33,000 prescriptions for controlled substances that Merrill wrote between January 2001 and May 2004.

Merrill operated a clinic in Apalachicola, Florida from 1994 until 2004. In January 2006, a jury in the U.S. District Court for the Northern District of Florida convicted Merrill on ninety-eight (98) of the 100-count indictment filed against him, and, in July 2006, he was sentenced to serve various concurrent sentences, including life imprisonment.

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**Georgia Appeals Court Affirms
Dismissal of Claims over Withdrawal of
Life Support**

A Georgia appeals court ruled recently against parents claiming wrongful withdrawal of their minor daughter's life support by her physician, as well as claims that the hospital where she was being treated intentionally injured her or caused her death. *Ussery v. Children's Healthcare of Atlanta Inc.*, No. A07A2222 (Ga. Ct. App., Jan. 23, 2008).

The Georgia Court of Appeals ruled that the estate and parents of Ella Ussery could not recover for the intentional tort of wrongful removal of life support. In its decision, the court held the evidence showed that Ella was unlikely to recover from a severe brain injury and that her parents consented to the removal. In addition, the court found the recommendation that life support be withdrawn was made only after Ella's treating physician, Dr. James Jose, consulted with two nontreating physicians.

In a separate finding, the appeals court said Children's Hospital of Atlanta, known as Scottish Rite Children's Medical Center at the time Ella was injured following surgery, was entitled to assert state peer review privilege with respect to certain incident reports that were compiled concerning the underlying incident.

**Court Dismisses FCA Action, Finding
Itemized Charges Immaterial to PPS
Payment**

On February 11, a federal district court dismissed a False Claims Act *qui tam* action filed by a former employee alleging that a hospital submitted fraudulent claims to Medicare, after finding that the charges on a patient's bill were immaterial to the amount of reimbursement under Medicare Part A. *United States v. St. Joseph's/Candler Health System Inc.*, No. 4:04-cv-00190-WTM-GRS (S.D. Ga., Feb. 11, 2008).

The whistleblower alleged in the FCA complaint that St. Joseph's/Candler Health System, Inc. submitted false claims to Medicare for reusable equipment and routine services as separately billable items, instead of bundled together as required by Medicare rules. The U.S. District Court for the Southern District of Georgia held that the whistleblower failed to state a claim because they do not allege a material falsity that could result in a loss to the public. The district court found that the allegedly improper practices would not be material under any standard to claims submitted to the government.

District Court Judge William T. Moore, Jr. wrote in his opinion, "Because the [prospective payment system ("PPS")] pays a standard rate based on the patient diagnosis and the [diagnostic related group] code, the itemized charges on a patient's bill are immaterial to the amount of reimbursement a provider receives from Medicare Part A," and further held; "Accordingly, even if [Digiovanni] proves that St. Joseph's/Candler was improperly including charges for reusable equipment in claims submitted to Medicare, this improper submission of claims would have no effect on the amount of reimbursement."

PHARMACEUTICAL LIABILITY

**Tort King Gets Big Win for Alabama
Medicaid**

The [Wall Street Journal](#) reported a \$215 million judgment was awarded against AstraZeneca Pharmaceuticals LP by an Alabama State court jury in a Medicaid drug-price-fraud suit. The suit alleged AstraZeneca made Alabama's Medicaid pay too much for drugs prescribed to its patients by inflating prices. However, AstraZeneca contended that "it had obtained for the state the best price it could for its drugs." [Wall Street Journal](#), B6, Feb. 22, 2008.

According to [Bloomberg](#), after a short deliberation, the Jurors in Montgomery County Circuit Court found the company liable for misrepresentation and fraudulent concealment and awarded \$40 million in compensatory damages and \$175 million in punitive damages. This case is the first of more than seventy (70) drugmakers sued by Alabama to go to trial. [Bloomberg](#), Feb. 22, 2008.

Dey and Takeda Got Out of Dodge Early

A few weeks prior to this massive award, Dey, LP and Takeda Pharmaceuticals North America, Inc. agreed to pay the State of Alabama \$4.75 million and \$2 million, respectively, to settle.

The States' King's lawsuit is ongoing against 71 other defendants. Four defendants are scheduled to go to trial in February in Montgomery County Circuit Court.

FRAUD & ABUSE

**Group May Prepare Radiology Reports
without Charge to Critical Care Hospital**

The Department of Health and Human Services Office of Inspector General ("OIG") said in a

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recent advisory opinion that a radiology practice group can prepare, without charge, written reports of its interpretations of radiology tests for a critical access hospital without risking administrative sanctions or civil monetary penalties.

OIG said that, in accordance with Medicare payment rules, radiologists who are reimbursed for professional interpretations are obligated to prepare written reports for hospital patients as part of the covered professional service.

The hospital is not obligated to incur the costs of preparing a written report documenting professional services of radiologists provided to its patients the opinion further stated.

As such, OIG concluded that the reports for Medicare patients do not constitute remuneration to the hospital. Op. Off. Insp. Gen. No. 07-19 (Jan. 3, 2008). To read more about OIG 07-19, go to <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-19C.pdf>.

Fifth Circuit Finds No Intent by Physicians to Submit False Bills to Medicare Program

A federal appeals court recently held that the office manager of a medical facility providing orthopedic care failed to show the facility and its physicians knowingly or recklessly cheated the government to obtain higher Medicare payments. *United States ex rel. Vick v. Smith*, No. 06-51386 (5th Cir., Jan. 4, 2008).

The U.S. Court of Appeals for the Fifth Circuit, governing Mississippi, Texas and Louisiana, found that neither the whistleblower, Margaret Taylor Vick, nor her expert witness had personal knowledge of whether the physicians facility in Midland, Texas, had the intent necessary to be liable under the False Claims Act.

The whistleblower alleged the physician used codes requiring he spend fifteen (15) minutes with each patient, which would be impossible because the physician saw fifty (50) to eighty (80) patients each day.

The Judge wrote in her opinion "Indeed, Vick cannot point to a single instance in which [the physicians and Southwest] submitted a false claim to Medicare, let alone an instance in which [they] knowingly or recklessly submitted such a claim".

She also wrote that, "[f]or her part, [the expert witness] did identify what she believed to be a pattern of erroneous billing that might support an inference of scienter, but at the same time

[the expert witness] acknowledged that this erroneous billing included not only over-billing but also under-billing showing that [the physicians and Southwest] were merely negligent billers, which does not offend the FCA".

OIG Approves Gainsharing Arrangements Involving Cardiac Surgeons, Anesthesiologists

OIG has given its blessing to two separate gainsharing arrangements involving shared cost-savings between hospitals and an anesthesiologist group and a cardiac surgeon group.

OIG said that both arrangements raised concerns under the civil monetary penalty ("CMP") provision for offering to induce physicians to reduce or limit services, even though some of those services may not have been medically necessary.

Nevertheless, OIG said it would not seek sanctions against the hospitals in connection with either of the arrangements because of specific safeguards in the arrangements.

In both arrangements, the hospital hired a program administrator to identify cost-savings that the physicians could achieve by changing certain standard practices. The program administrator based the cost-saving recommendations on a study of historic practices among the anesthesiologists and cardiac surgeons during cardiology procedures.

In the case of both arrangements, OIG listed eight specific safeguards it considered when deciding it would not seek sanctions. First, the cost savings were clearly identified, and OIG did not see a reduction in patient care. The surgical group also notified patients regarding the arrangement. Moreover, the group distributed the profits on a per capita basis, which reduced the likelihood of disproportionate cost savings.

In the opinion, OIG commented "[W]hether current medical practice reflects necessity or prudence is irrelevant for the purpose of the CMP". Op. Off. Insp. Gen. No. 07-21, No. 07-22 (Jan. 14, 2008). To read more about OIG 07-21, go to <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-21A.pdf>. To read more about OIG 07-22, go to <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-22A.pdf>.

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OIG Approves Prompt-Pay Discounts

In its Advisory Opinion 08-03, OIG analyzed a healthcare system's provision of prompt pay discounts to inpatients and outpatients, and concludes that while the program could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce referrals were present.

Under the proposed arrangement, the three-hospital healthcare system would offer a discount to patients, including federal healthcare program beneficiaries and other insured patients, for prompt payment of their cost-sharing amounts and amounts owed for non-covered services. The program is structured to reduce the healthcare system's collection costs and the discount (5-15% of bill amount), would bear a reasonable relationship to the system's avoided collections costs. The program would be offered to both inpatients and outpatients, regardless of ability to pay.

Under the program, the system would not publicly advertise the prompt pay program and patients would only be informed of the availability of the discount when the patient registered for outpatient services and paid his or her cost-sharing amount, when written statements were sent to the patient by mail, and when financial arrangements were made with the patient after admission for inpatient services. The system would notify all payers of the program and all costs associated with administering the program would be handled by the system.

OIG determined that, because of the following program features, the risk was sufficiently reduced: (i) the discount would not be publicly advertised and the patient would only be informed of the discount during the billing process; (ii) third-party payers would be notified of the discount program; (iii) the costs of the discount program would be borne solely by the healthcare system; and (iv) the amount of discounted fees would bear a reasonable relationship to the amount of avoided collection costs.

OIG would not impose administrative sanctions and that no grounds for imposing civil monetary penalties would exist. Op. Off. Insp. Gen., No. 08-03 (Feb. 8, 2008). To read more about OIG 08-03, go to <http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-03A.pdf>.

OIG Approves Program of Free Drugs to Poor

In Advisory Opinion 07-18, OIG analyzed programs operated by tax-exempt, nonprofit,

and charitable organizations to subsidize cost-sharing amounts and premium obligations associated with outpatient drug treatment received by Medicare and Medicaid beneficiaries with certain chronic diseases. In its opinion, it concluded that it would not seek to impose administrative penalties under the civil monetary penalty provision ("CMP") prohibiting inducements to beneficiaries or the anti-kickback law.

This advisory opinion identifies a foundation's administrator as a healthcare consulting company with commercial clients that include pharmaceutical manufacturers whose products may be used by patients receiving grants from the foundation. The administrator is a subsidiary of a leading pharmaceutical distributor.

OIG separately analyzes the two payment aspects of the programs. First, it considered the contributions of the donors (primarily the pharmaceutical manufacturers) to the foundation. Second, OIG considered the grants from the foundation to Medicare and Medicaid beneficiaries.

With respect to the donor contributions to the foundation, OIG evaluated the foundation's design and administration to confirm that it is an independent, *bona fide* charitable organization acting as a go-between for donors and patients to "effectively insulate" beneficiary decisionmaking from donations.

The foundation's use of a compliance auditor and an independent review organization to monitor the "ethical wall", and the independence of the Foundation's programs, was also cited by OIG. Op. Off. Insp. Gen., No. 07-18 (Jan. 3, 2008). To read more about OIG 07-18, go to <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-18E.pdf>.

CON

Certificate of Need Rules Properly Applied By Statewide Council, Alabama Court Decides

An Alabama state appeals court ruled recently that Alabama's health care facility planning council did not violate state certificate of need ("CON") laws or procedural requirements in making an adjustment to the state health plan to accommodate construction of a new 60-bed hospital in Madison, Alabama. *Health Care Authority of Athens and Limestone County v. Statewide Health Coordinating Council*, No. 2060385 (Ala. Civ. App., Jan. 18, 2008).

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The Health Care Authority of Athens and Limestone County challenged the process used by the Statewide Health Coordinating Council and other state officials to make an adjustment to the state plan that governs CON determinations made by the State Health Planning and Development Agency ("SHPDA"). This challenge was rejected by the Alabama Court of Civil Appeals.

The court ruled that the Alabama Administrative Procedure Act ("APA") did not require the council to comply with rulemaking procedures in adopting the plan, which stated that the city of Madison in Madison County needed its own hospital with up to 60 beds. The court provided that plan "adjustments" are not "rules" governed by the state APA and the adjustment did not authorize a CON, but merely was the first step in the CON issuing process.

MEDICAID

CMS Proposed Rule Outlines Standards for Self-Directed Personal Assistance Care

The Centers for Medicare & Medicaid Services ("CMS") recently published a proposed rule providing guidance to state Medicaid officials who want to administer self-directed personal assistance services ("PAS").

The proposal will allow Medicaid recipients needing help with the activities of daily living to select, direct, and manage their needed services under an individualized service plan and budget. This self-directed care lets recipients retain control and authority over who provides the services, how the services are provided, the hours they work, and their rate of pay.

CMS said states choosing this self-directed care option must have necessary quality assurances and other safeguards in place to assure the health and welfare of participants. States also must train potential participants in ways to manage their budgets and assess their personal care needs.

Alabama is the first state to receive federal approval to allow self-directed personal assistance services ("PAS") as a feature of its Medicaid plan. Under Alabama's plan, participants will be able to hire legally liable relatives to provide care and to use their service budgets to pay for items that increase their independence or substitute for human assistance. Alabama's plan will also permit participants to receive some "cash" so that goods and services can be purchased directly.

NURSING HOMES

Arbitration Clause Signed by Daughter Held Invalid in Suit against Nursing Home

In a decision earlier this year, the Mississippi Supreme Court ruled that a nursing home cannot compel the daughter of a deceased resident to arbitrate her claim against the facility because it did not present evidence that she had authority to bind the resident to an arbitration clause contained in the admission contract. *Mississippi Care Center of Greenville LLC v. Hinyub*, No. 2005-CA-01239-SCT (Miss., Jan. 3, 2008).

Plaintiff Nancy Hinyub, individually and as the personal representative of her late father, Don Wyse, brought a wrongful death action against defendants, the Mississippi Care Center of Greenville LLC ("MCCG"), Oxford Management Co., Michael Overstreet, and Tessa Cooper. The defendants moved to compel arbitration based on a nursing home admission agreement entered into between the parties that contained an arbitration provision. Defendant's motion was denied by the trial court, and the defendants appealed.

The state high court affirmed in an opinion by Justice George Clarence Carlson, Jr. Although there is a liberal federal policy favoring arbitration, it said, arbitration is a matter of contract, and a party cannot be compelled to submit to arbitration any issue that he or she has not agreed to submit.

PEER REVIEW

High Court Declines Review of Decision Rejecting Privilege in Discrimination Case

The U.S. Supreme Court rejected a petition seeking review of a federal appeals court decision that allowed discovery of peer-review materials in a lawsuit alleging racial discrimination in a decision on January 7. *Christie v. Adkins*, No. 07-538 (U.S., Jan. 7, 2008).

This action by the Supreme Court leaves a June 2007 decision by the U.S. Court of Appeals for the Eleventh Circuit, which ruled that Georgia's medical peer-review privilege protecting physician performance assessments from discovery and disclosure in medical malpractice cases did not apply to discrimination claims brought in federal court is left intact.

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In their October 22 petition, the Georgia hospital, and the physicians who participated in a challenged peer-review proceeding, claimed that the high court should overturn the appeals court's decision and recognize an evidentiary privilege against compelled disclosure of confidential, internal medical peer-review communications under Rule 501 of Federal Rules of Evidence.

In its decision, the Eleventh Circuit acknowledged that most states have peer-review privilege statutes and that they serve a number of important interests, including the promotion of vigorous oversight of physician performance. Those privileges must, however, "be considered against a corresponding and overriding goal--the discovery of evidence essential to determining whether there has been discrimination in employment," the court said.

The court concluded that, on balance, the interest in facilitating the elimination of employment discrimination outweighed the "extraordinary protection" afforded by state medical peer-review privilege laws. The ruling marked the third time a federal appeals court has refused to recognize a state peer-review privilege where a countervailing and compelling government interest was at stake. *Adkins v. Christie*, 488 F.3d 1324 (11th Cir. 2007).

Muslim Doctor Produced Evidence of Pretext Sufficient to Send Retaliation Case to Trial

The U.S. Court of Appeals for the Fifth Circuit ruled recently that a physician whose services were terminated by a Veterans' Administration ("VA") hospital just three hours after he made a verbal Equal Employment Opportunity ("EEO") complaint raised sufficient evidence that the reasons for his discharge were pretextual, thereby entitling him to go to trial on a retaliation claim. *Rikabi v. Nicholson*, No. 07-60041 (5th Cir., Jan. 23, 2008).

A summary judgment granted to VA was reversed by the court because there was sufficient evidence to create a genuine issue of material fact on whether VA's explanation for the adverse employment action was a pretext for retaliation.

A naturalized citizen of the United States, Dr. Khaled Rikabi is a Muslim of Lebanese origin and an expert in infectious diseases. Rikabi began working as a staff physician at a VA hospital in 1996. After the events that took place on September 11, 2001, he said, he noticed an increase in anti-Muslim sentiment at the medical center. In fact, his supervisor's wife, who worked as a secretary at the center, informed him that both she and her husband disliked

Muslims. Also, Rikabi alleged, the center's chief of staff openly stated that Muslims were "a threat to the United States."

Rikabi was terminated in March 2003 by the chief of staff for the stated reason that his services were no longer needed. However, the following June, Rikabi learned that the center had issued a recruiting announcement for the position from which he was terminated. Rikabi subsequently made a verbal EEO complaint, stating that he had been discriminated against on the basis of religion and national origin. Three hours after Rikabi submitted his EEO complaint, the chief of staff announced that any patient at the center needing an infectious disease consultation should not be seen by Rikabi.

EMTALA

State Court Says Unborn Child Qualifies As Inpatient under Provisions of EMTALA

Of healthcare legal interest outside the South, a Wisconsin appeals court recently ruled when a hospital provides inpatient care to a woman that involves treating her fetus simultaneously, the unborn child is considered a second inpatient, admitted at the same time as the mother, for purposes of the applicability of the Emergency Medical Treatment and Labor Act screening requirement. *Preston v. Meriter Hospital Inc.*, No. 2006AP3013 (Wis. Ct. App., Jan. 24, 2008).

The Wisconsin Court of Appeals concluded that, for purposes of coverage under the EMTALA screening requirement, both the mother and unborn child were inpatients at the time of the child's birth as a matter of law.

COMMENTARY

The Perfect Storm: Recent Decisions Tilt Litigation Playing Field toward Plaintiffs in Alabama

Several recent court decisions by the Alabama Supreme Court and the Eleventh Circuit have shifted the litigation playing field toward plaintiffs. These decisions may open the door for plaintiffs to bypass strict judicial review of class actions, to avoid removal of cases from state to federal court, to subject defendants to broader discovery, and to file toxic exposure claims under a new more liberal statute of limitations.

Class Actions Inside Arbitration: In response to class action abuses in the 1990s, Alabama's

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Supreme Court and Legislature adopted tough judicial review standards for class action certification orders. In *Ex parte Johnson*, Nos. 1061760 & 1061762, 2008 Ala. LEXIS 21 (Ala. Jan. 25, 2008), plaintiffs sought to avoid that tough judicial review by seeking class treatment of mobile home defect claims inside an arbitration proceeding rather than a lawsuit. The mobile home manufacturer defendants obtained judicial stays of arbitration from trial courts. The manufacturers asserted that class arbitration was inappropriate based on a venue clause in the arbitration agreement. The Supreme Court lifted the stays, holding that the arbitration agreements incorporated AAA rules that authorized arbitrators to decide whether the contract permitted class arbitration. Although judicial review may be available after the class certification decisions are made, such review may be very deferential. Whether arbitration clauses can bar class arbitration is being litigated across the country. The U.S. Supreme Court will soon decide whether arbitration clauses can provide for searching, as opposed to deferential, judicial review. Businesses should review their arbitration clauses and consider whether to incorporate class action defenses.

Removal at the Plaintiff's Option: In response to class action and mass action abuses, Congress passed the Class Action Fairness Act ("CAFA") that allows the removal to federal court of "mass actions"—actions involving more than 100 plaintiffs and more than \$5 million. In *Lowery v. Alabama Power Co.*, 483 F.3d 1184 (11th Cir. 2007), the Eleventh Circuit overruled decades of diversity removal jurisprudence in a mass action removed from state court under CAFA. The court held that where the complaint does not state the amount in controversy, a defendant can base removal only on evidence that is received from the plaintiff or the state court. Arguments regarding the type of claims and similar cases are no longer sufficient, and federal discovery is no longer available. The opinion apparently applies to all removals, not just those brought under CAFA.

Broader Discovery: In the 1990s, the Alabama Supreme Court reined in overbroad discovery requests that were unduly burdensome on defendants. This was especially important to companies with thousands of customer files. In *Ex parte Cooper Tire & Rubber Co.*, No. 1050638, 2007 Ala. LEXIS 229 (Ala. Oct. 26, 2007), the Supreme Court held that where trial courts in other States had allowed discovery of voluminous files, it would not be burdensome for an Alabama trial court to do the same. While the sought-after items must still be relevant, the burden on the defendant may no longer be decisive if any trial court in the country has previously ordered that discovery.

Liberalized Statute of Limitations for Toxic Torts: For almost thirty years, the two-year limitations period for most toxic torts in Alabama began to run with the date of exposure. This resulted in unfairness to plaintiffs for whom adverse health effects did not become apparent until more than two years after exposure. In *Griffin v. Unocal Corp.*, No. 1061214, 2008 Ala. LEXIS 19 (Ala. Jan. 25, 2008), the Supreme Court overruled three decades of precedent, including a decision just last year, to hold that a toxic exposure injury accrues when there is a "manifest, present injury." An injury becomes "manifest" when there are "observable signs or symptoms or the existence of which is medically identifiable." The Supreme Court made the new rule prospective.

The rise of mass actions, the restriction of removal, broader discovery, and a more liberal statute of limitations generally favor plaintiffs. If two or three of these developments combine in a single case, an unprepared business could face the perfect storm.