

# Massachusetts Medical Law Report

Legal news for the medical community

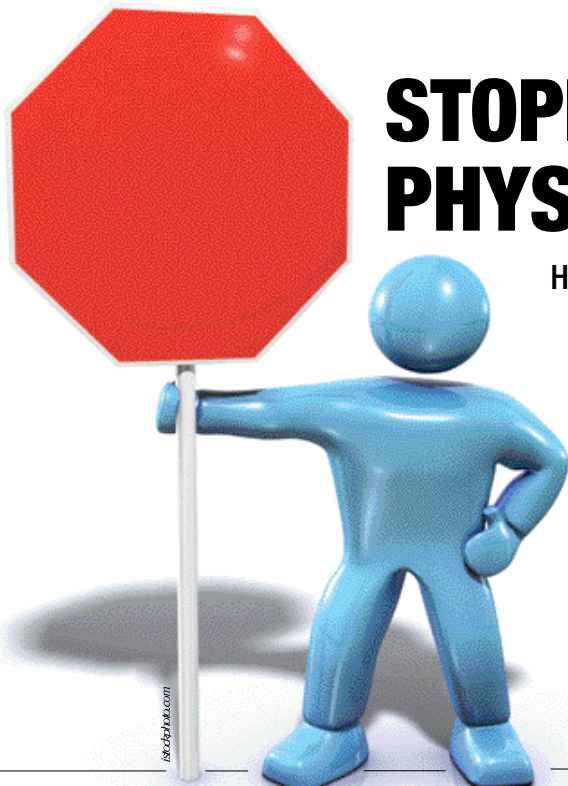
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Lawyers Weekly  
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Vol. 4, No. 1  
Autumn 2008

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## STOPPING DISRUPTIVE PHYSICIAN BEHAVIOR

### Hospitals must revise policies under new standard

By Eric Berkman

Imagine a nurse being so intimidated by a condescending and abusive doctor that she decides not to contact him for an emergency while he's on call.

Or perhaps a patient suffering from internal bleeding but refusing treatment when he sees his doctor screaming at the nurses. Or a doctor loudly refusing to listen to his nurses, undoing a course of treatment and causing the death of a patient.

While these scenarios may sound like a bad ER script, they've actually happened, according to anonymous comments submitted by nurses, technicians and physicians who responded to a national survey on disruptive physician behavior and the risks it creates in the clinical setting.

As a result of these risks, the Joint Commission announced a new standard in July addressing "behaviors that undermine a culture of safety."

The standard requires accredited hospitals and health organizations to maintain a code of conduct that defines "acceptable and disruptive and inappropriate behaviors" and requires organizational leaders to create and implement a process for managing disruptive and inappropriate behaviors.

Doctors and health care lawyers welcomed the new standard, saying the failure of many hospitals to police the issue on their own has put patients in harm's way and heightened the risk of liability due to bad medical outcomes or hostile work environments.

"With the improvement of health care in general and the demand that patients be provided good care, this has been recognized as an area that hasn't really been addressed," says Luis Sanchez, director of Physician Health Services, a subsidiary of the Massachusetts Medical Society that provides consultation and support to doctors struggling

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## Doctor can be sued for patient's lost chance of survival

By David E. Frank

In a pair of closely watched cases that significantly expand the types of claims plaintiffs can bring against doctors in medical malpractice cases, the Massachusetts Supreme Judicial Court has decided that state law for the first time will permit "loss of chance" recovery.

The "loss of chance" theory aims to hold a doctor responsible for a reduction in a patient's statistical chance of survival or chance of avoiding becoming disabled.

Loss of chance has been claimed in a variety of contexts, including failure to call for emergency help, failure to promptly admit or transfer a patient to a hospital, failure to perform surgery and failure to prescribe cancer treatment.

One of the two cases the court considered,

*Continued on page 15*

## Mass. doctor prosecuted for patient's death

### Rare criminal case over patient care has physicians concerned

By Eric Berkman

As state authorities bring what is believed to be the first-ever criminal prosecution in Massachusetts against a physician for negligence in the treatment of a patient, doctors have yet another source of stress.

Attorney Paul Cirel of Dwyer & Collora in Boston, who is defending the physician, says the indictment of his client, a Cape Cod obstetrician whose alleged negligence in an abortion procedure caused the death of a patient, signals a "dark day" for physicians in the Commonwealth.

"This is criminalizing professional medical conduct at some level, and that's the ultimate sanction in the law," he says. "To try to make fine distinctions beyond negligence and to criminalize bad outcomes — I think that can be a very scary process for doctors."



AP Photo/Cape Cod Times/Svein Hesselip

Attorney Paul Cirel (left) is defending Dr. Rapin Osathanondh (right).

However, many lawyers say that if the allegations in this case — including the doctor's alleged failure to monitor the patient's pulse and blood pressure while she was under anesthesia, delay in calling 911 for assistance and attempt to cover up his actions from the Board of Registration in Medicine — are true, most physicians should have little to worry about.

After all, this set of facts is unusually egregious, and criminal prosecutions for medical negligence are exceedingly rare. Lawyers say a case of medical malpractice would only become criminal if it involved willful and wanton conduct on the part of the doctor. "What would make this case criminal, and it may be a tough criminal case, is the extreme nature of the lack of patient safety mechanisms," says David M. Gould, a malpractice-defense lawyer with

*Continued on page 7*



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Please post comments on the site or send me an e-mail at reni.gertner@mamedicallaw.com to let me know what you think.

— Reni Gertner, MPH

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# 'Medical credit cards' could lead to suits against doctors

By Sylvia Hsieh

Many doctors and dentists across the country are marketing medical credit cards to their patients, but lawyers say that in some cases they could lead to lawsuits against providers.

The cards could lead to a host of claims under state laws – such as unfair and deceptive practices and predatory lending statutes – being brought against a medical provider for not making proper disclosures.

Many doctors like the cards because they get paid immediately from the credit card companies rather than spending time collecting bills.

But consumer lawyers say they are seeing a growing number of cases where patients say they did not realize they had signed up for a credit card and did not understand its terms and conditions, such as interest rates of up to 27 percent.

"It's becoming more and more of an issue. Doctors are marketing them as a means of financing, but the staff is not adequately explaining what the product is and they're putting their patients in difficult financial predicaments," said Gina Calabrese, a law professor and associate director of the elder law clinic at St. John's University School of Law in New York.

Patients are being pitched the cards not only before elective procedures, but also when they are in need of urgent care or not in a position to make financial decisions.

"This is definitely happening with dentists where people are coming in with excruciating pain and need to have it solved right then," said Claudia Wilner, a staff attorney with the Neighborhood Economic Development and Advocacy Project in New York City.

The issue of voluntariness has become enough of a concern that in California a bill has been introduced to prohibit dentists from offering financing to patients while under anesthesia.

## Rx for debt

Lenders are capitalizing on the vast amounts consumers spend on medical bills by marketing credit cards specifically for health care expenses, such as Citi Health Card, GE CareCredit and Chase Health Advance.

Even some hospitals, physician and dental practices have gotten into the market by issuing their own branded credit cards.

Americans spent approximately \$265 billion on out-of-pocket medical expenses last year, not including insurance premiums, said Mark Rukavina, director of The Access Project, a medical debt research and advocacy group in Boston.

"Tailoring a card to meet the needs of people paying nearly \$300 billion seems to be a smart business move from the financial services perspective," he said, adding that two-thirds of people with medical debt have insurance.

Typically, a patient is offered financing for procedures that aren't covered by insurance or where the patient is uninsured.

This is not only happening for elective procedures, Rukavina said.

"We've heard complaints from people who signed up for a credit card or revolving line of medical health credit to help pay for routine care or costs associated with chronic care," he said.

Lawyers contend that medical providers are not adequately explaining what a patient is signing up for. In many cases, patients think they are being offered a payment plan by the medical provider, not a credit card by a commercial bank.

"Sometimes the doctor's office will say they don't have to start paying now, so patients think they are getting flexibility in a payment plan with the doctor's office.

They're asked to sign a lot of papers and often it's not until later when they receive a bill they realize they have a credit card," said Wilner, who said that one of her clients thought she had signed up for health insurance.

Like other credit card offers, medical credit cards often have low or zero interest for an introductory period. But that can change quickly.

Depending on the terms and conditions, some credit cards can jump from zero to 27 percent interest based on a triggering event, like a late payment.

Cards with "universal reporting," for ex-



ample, can trigger a jump in rates if the consumer is late on any credit card, even from a different creditor, Rukavina said.

"There's very little regulation of credit cards, interest rates [or] the size of late fees,

so people's medical debt can climb at amazing rates. If a person misses a payment or is late on a payment, he is subject to skyrocketing interest rates. It ends up being extremely expensive and often cannot be paid," said Wilner.

Many cases are already in collection by the time a lawyer sees them.

Another emerging trend is that some health care providers are checking the credit scores of patients before treatment and credit scoring companies are creating a special credit score for medical debt.

While it is not necessarily inappropriate for a medical provider who is acting as a creditor to run a credit check before ex-

*Continued on page 15*



**MARCH 5, 10:40 AM**

You respond to a request from The Center for Medicare Services for 100 of your patients' charts.

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# Listening In

The news beat of the medical profession



## Insurers push P4P

Massachusetts insurers are increasingly rewarding doctors and hospitals that take steps to reduce errors and improve management of some of the most expensive diseases – and by extension punishing doctors and hospitals that fall short in key quality areas, according to the Boston Business Journal.

With pay-for-performance programs, insurance companies stand to save huge sums of money. Eliminating hospital-acquired infections alone could save up to \$400 million a year in Massachusetts, according to one estimate.

Hospitals and doctors that reach benchmarks established by insurers stand to see reimbursements increase in the short

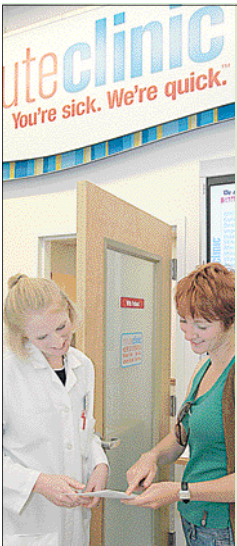


term and patient referrals increase over time.

On the other side of the equation, health care providers that fail to meet standards of care stand to lose business as insurers steer members elsewhere.

In Massachusetts, doctors and hospitals have generally been paid by the procedure. The only exception was a short-lived capitation system during the 1990s.

About 25 percent of Harvard Pilgrim's members' doctors have traditional contracts, while 60 percent are treated by doctors in pay-for-performance contracts. Tufts Health Plan has been engaged in similar initiatives, according to the Journal.



AP Photo/Andy King

## Insurers will cover retail clinic visits

Some of the state's largest health insurers say they will cover visits to the retail health clinics expected to open in CVS and Walgreens drugstores later this year, according to the Boston Globe.

Harvard Pilgrim Health Care and Tufts Health Plan have signed contracts with CVS Caremark, the Woonsocket, R.I., company that operates more than 6,000 pharmacies nationwide.

The chain plans to open as many as 28 MinuteClinics in its Massachusetts stores this year and 100 statewide within five years.

CVS also is negotiating coverage for clinic services with Blue Cross and Blue Shield of Massachusetts, the state's largest insurer.

Retail clinics in Massachusetts will feature weekend and evening hours. Services will include vaccinations and treatment of common ailments such as ear infections, poison ivy, and minor burns. Without insurance, prices range from \$59 to \$69 at CVS's MinuteClinics, and from \$59 to \$74 at Walgreen clinics.

While the clinics could ease crowding in hospital emergency rooms, a significant shift of patients away from emergency rooms could also hurt community hospitals that are strapped for cash and depend on steady revenue from emergency visits.

For a story about the possible legal issues that may arise from pharmacy-based clinics, see "Minute clinics raise round-the-clock risks," Massachusetts Medical Law Report, Spring 2008. Search terms for MMLR website: Berkman and clinic.

## Health management company unveils social network

WellNet Healthcare, a health management company in Bethesda, Md., is launching a virtual health clinic for physicians, pharmacists and patients.

Point to Point Healthcare will allow doctors to pull up online medical profiles and chat, via instant messaging, with patients. Patients will also be able to schedule checkups online, create a wellness journal or rate their

general practitioners, according to the Washington Post.

The new system lets employees create a personal network uniting their insurance claims manager with multiple doctors and pharmacies to better coordinate treatments. An online concierge helps workers find new specialists and a message system reminds them to pick up prescriptions.

The company said its online workspace will be guarded by the legal protections specified by the Health Insurance Portability and Accountability Act (HIPAA) and the same online security used by the banking industry.

Much like Facebook users, Point to Point members, who must opt in, can control who can see the different parts of their medical profile, the Post reported.

## Records may omit half of patients' problems

Patients interviewed after they have left the hospital report twice as many complications as their medical records suggest, according to a recent survey.

Researchers from Massachusetts General Hospital, Dana-Farber Cancer Institute and the Department of Public Health asked nearly 1,000 patients at 16 hospitals about infections, medication errors or reactions, and other incidents in a telephone survey, the Boston Globe reported.

Their accounts were reviewed by two doctors. Then their medical records were examined by experts to see if the problems surfaced there.

More than one in four patients reported a problem, but only about one in 10 medical records showed anything went wrong, according to the study, which appeared in the *Annals of Internal Medicine*.

However, some of the symptoms apparently developed after the patient left the hospital. Life-threatening or serious problems were more likely to be reflected in both the medical record and in interviews with the patient, the Globe reported.

## Doctors, TV ads help to cut smoking sharply

Nearly 8 percent fewer Massachusetts adults smoked in 2007 than the year before, the steepest decline in cigarette use in more than a decade, state health authorities reported.

The drop coincided with the revival of the state's tobacco-control program, which was slashed under the administrations of Jane Swift and Mitt Romney, according to the Boston Globe.

The Department of Public Health, for example, in boosting its spending by 50 percent, resurrected television ads starring former smokers whose health was affected by cigarettes.

At the same time, the state's quest to insure nearly every resident, which has extended cov-

erage to more than 350,000 adults, may have contributed to the decline.

"When we looked at studies about who influenced decisions about ending smoking, the primary care doctor was at the top of the list," said John Auerbach, the state's public health commissioner.

The one-year decline in smoking has been even more pronounced among adolescents, previously released figures showed.

In 2007, 17.7 percent of adolescents said they smoked regularly, down from 20.5 percent the year before, the Globe reported.



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## Hospital finances are on the decline

A leading industry association says that expenses are rising faster than payments can keep up with them at one-third of Massachusetts hospitals, according to the Boston Globe.

The financial condition of two-thirds of the state's 65 acute-care hospitals became worse in the first half of fiscal 2008, according to a Massachusetts Hospital Association analysis of figures from October through March.

For 37 percent of hospitals, their operating margin – how much income from providing pa-

tient care is left over after paying for certain costs – was negative. Also, for 37 percent of hospitals, their total margin – which reflects income from all sources – was negative after expenses were taken into account.

Hospital expenses grew by 7.6 percent between March 2007 and March of this year, with payroll and benefits increasing the most.

Medicare's adjustment for inflation rose 3.3 percent. Revenues from patient care climbed 7.5 percent during those 12 months, the Globe reported.

## Drug giant to pay over \$9M to Mass. Medicaid

International drug maker Bristol-Myers Squibb Co. has agreed to pay the state's Medicaid program \$9.2 million to settle a variety of allegations of improper sales, marketing and other business practices, the state attorney general's office announced.

The agreement comes after a four-part, seven-year investigation that began in 2001, the attorney general's office said. The probe was coordinated with the federal government and other state attorneys general, according to the Boston Globe.

The complaint alleged that the company and a subsidiary

paid "improper inducements" to pharmacists and wholesalers to increase the market share of its products.

The attorney general also alleged that the company instructed its sales staff to promote the use of an antipsychotic drug for children when the FDA had not approved the drug for use in children.

The Department of Justice announced the federal component of the settlement last September. The attorney general's office said that the total value of federal and state settlements to Medicaid programs nationwide is about \$389 million, the Globe reported.

# Verdicts & Settlements

## Patient fakes surgical injury, caught on video

The Berkshire Superior Court has concluded that the plaintiff in a medical malpractice case against a Pittsfield physician and Berkshire Medical Center "engaged in a willful and egregious pattern of concerted and consistent deception" in asserting claims that were "wholly insubstantial, frivolous and not advanced in good faith."

The court awarded the physician and hospital \$287,000 in fees and court costs.

The 24-year-old patient claimed that, immediately following a 2002 surgical implant procedure, she suffered a spinal cord injury that left her lower extremities paralyzed.

In graphic terms, she asserted repeatedly in her pleadings, answers to interrogatories and deposition testimony that she had lost all sensation in her legs and the ability to voluntarily move them.

She claimed in sworn testimony that she could only walk "using [her] hip flexors and forearm crutches to swing and drag [her] legs" and that she "has no ability to raise her legs or even wiggle a toe."

Discrepancies between her descriptions of her injuries and entries in her medical records at various health care facilities throughout the Northeast led the hospital to question the veracity of her claims.

The hospital hired a private investigator to observe and videotape her daily activities. The court described the contrast between the plaintiff's sworn testimony and the video evidence as "startling, even to someone inured to exaggeration and hyperbole that sometimes accompanies a personal injury action."

The videotapes, taken on 13 occasions over a span of 18 months, showed the plaintiff "engaged in such activities as bending, lifting, kneeling on the seat of a car and entering a car without assistance," the court noted. The tape also showed her driving a normally equipped car and "walking as normally as most people."

The court said that the plaintiff's "attempt to deceive is no better illustrated than by video footage" taken as she was entering and leaving her deposition.

In contrast to all of the video footage taken at and around her hometown in upstate New York both before and after the deposition, the deposition day footage shows her as "significantly disabled" with "her legs virtually useless."

The court also noted that "the plaintiff's husband, mother and father were all aware of, and personally witness to, the plaintiff's



actual physical capabilities, but nevertheless gave sworn deposition testimony that she was unable to walk."

After the deposition, Berkshire Medical Center made the videotape evidence available to the plaintiff's counsel, a major Boston personal injury firm. The firm promptly sought to withdraw from the case. The court permitted the woman to be represented thereafter, including at the hearing on sanctions and costs, by her father, a New York attorney.

**Type of action:** Medical malpractice  
**Injuries alleged:** Paralysis (plaintiff); fraud on the court, frivolous claim (defendant)

**Date:** March 10, 2008

**Submitted by:** Diane M. DeGiacomo and Lisa McCormack of Cain, Hibbard, Myers & Cook, Pittsfield (for Berkshire Medical Center Inc.) and Heather Beattie of Morrison Mahoney, Boston (for Gordon Kuhar, M.D.)

Massachusetts Medical Law Report compiles the summaries of verdicts and settlements on this page from reports sent by attorneys to us or to Massachusetts Lawyers Weekly. The report information is generally provided by one of the lawyers in the case, although occasional reports may be based on court records and news reports. We edit the material for style, grammar, length and, where appropriate, content. We are interested in printing verdicts won by both health care providers and plaintiffs, in addition to settlements.

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# Verdicts & Settlements

## Lupus medication causes patient's vision loss

In 2000, a 50-year-old female patient suffered from rheumatoid arthritis and lupus.

Her rheumatologist started her on hydroxychloroquine, but towards the end of 2000 switched her to chloroquine due to an allergic reaction.

Chloroquine, an anti-malarial drug used in the treatment of lupus, has a rare side effect of retinal toxicity resulting in vision loss. As a result, patients who are on chloroquine require periodic monitoring of their visual fields by their ophthalmologists.

The ophthalmologist examined the patient several times in the four years after she began taking chloroquine. The doctor performed no formal visual field testing during these visits, and attributed slight changes in visual acuity to presbyopia, or normal, aging-related visual changes.

In 2003, the patient complained of decreased vision. Amsler grid testing and funduscopy were normal, and she was referred to a neurologist, whose findings were also normal. The ophthalmologist finally performed visual field testing in 2004 that confirmed bilateral central scotoma, or blank spots, due to toxic damage to the retina. A subsequent work-up by retinal specialists

found bullseye maculopathy secondary to chloroquine toxicity.

The patient claimed that the doctor's failure to perform earlier visual field testing to detect her chloroquine retinopathy was negligent and caused her permanent visual damage.

The visual damage was such that she had significant blank spots in her central visual fields, but continued to work and to drive short distances.

She claimed that she told the ophthalmologist and her employees several times that she was on the drug chloroquine because she understood it could cause visual damage. The doctor denied ever knowing that the patient was on chloroquine prior to 2004, and the medical records contained no direct reference to the drug.

The case settled after depositions for \$1,250,000.

**Type of action:** Medical malpractice  
**Injuries alleged:** Diminished visual acuity and "blank spots" in vision  
**Date:** March 7, 2008  
**Submitted by:** Robert W. Casby and Benjamin R. Zimmermann of Sugarman & Sugarman, Boston (for the plaintiff)

## Surgeon operates on wrong vertebra

The case involved a 67-year-old woman with a long history of back pain.

Her pain had become more constant and developed into severe buttock pain radiating down both legs, which was aggravated with prolonged standing and sitting.

An MRI revealed that she had grade 2 spondylolisthesis at L4-L5 with marked spinal stenosis.

In August 2005, she was evaluated by an orthopedic surgeon, who recommended surgery. As a result, on Sept. 13, she underwent what was supposed to have been a decompression laminectomy at L4-L5 and fusion.

Immediately following the operation, the patient was in agony.

During subsequent rehabilitation, her severe pain persisted and she required a walker.

As a result, she had another MRI, which revealed that the surgeon operated at the wrong level, L3-4 instead of L4-5. The surgeon then informed her that he made a mistake and apologized.

In February 2006, she underwent a second operation, a laminectomy and fusion at the correct level, L4-L5.

Following the second operation, she underwent more rehabilitation. Due to the surgeon's error, she endured several additional




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months of pain, but was relatively fine several months following the second operation.

Unfortunately, due to her prolonged absence from work from the two surgeries and prolonged rehabilitation, she lost her part-time job at a nearby church.

The case settled for \$315,000.

**Type of action:** Medical malpractice  
**Injuries alleged:** Second operation, prolonged rehabilitation, lost wages  
**Date:** October 2007  
**Submitted by:** Lisa G. Arrowood of Todd & Weld, Boston (for the plaintiff)




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# Mass. doctor prosecuted for patient's death after abortion

Continued from page 1

Ficksman & Conley in Boston. "That's a quantum leap from doing something negligently. [Before this], we've never seen a prosecution of a licensed physician performing a procedure in a licensed facility."

Nonetheless, attorneys say the fact that such a prosecution is happening could still cause physicians here considerable angst. And it may even impact the way some of them practice.

"If a diagnosis is not timely made or an outcome from a surgical complication is adverse in the extreme, a physician now has to consider, 'Am I going to be sued? Am I going to lose my license? Or am I going to be prosecuted for homicide?'" says Martin Foster, a med-mal defense lawyer at Foster & Eldridge in Cambridge. "Whether [prosecution] occurs with frequency or infrequency, providers will now be thinking about it on a day-to-day basis."

## Tragic result

The defendant in the case is Dr. Rapin Osathanondh, a board-certified obstetrician/gynecologist who was a solo practitioner at the Women's Health Center in Hyannis.

On Sept. 13, 2007, Laura Hope Smith came to the defendant's clinic for an abortion.

According to the Massachusetts Board of Registration in Medicine's statement of allegations, the defendant sedated Smith without means of cardiac monitoring or blood-pressure monitoring and did not have oxygen available to administer to the patient.

The Board also alleged that an office worker with no training in CPR or other lifesaving measures was the only other staff member present.

The defendant, who was unable to awaken Smith after the procedure, allegedly de-

layed calling 911 for help. Smith was eventually transported to a hospital, where she was pronounced dead.

The Board further maintained that the defendant tried to cover up his negligence by telling Board staff that he had administered oxygen, he had monitored Smith's pulse, and his assistant was certified in life-saving procedures when, in fact, she was not.

Additionally, the defendant allegedly made structural changes to an adjacent room. When Board staff investigated the incident, he allegedly misrepresented that the adjacent room – which contained an oxygen tank, resuscitative equipment and monitoring devices – was where he performed the procedure.

In February 2008, the Board initiated disciplinary proceedings against the defendant, describing his actions as "gross misconduct" calling into question "his competence to practice medicine."

The defendant surrendered his medical license and was permanently barred from practicing medicine in Massachusetts.

Michael O'Keefe, district attorney for the Cape and Islands, subsequently commenced criminal proceedings against the defendant and secured an indictment for manslaughter in July.

The defendant pleaded not guilty in Barnstable County Superior Court and the case is currently proceeding toward trial.

O'Keefe could not be reached for comment.

## Cause for concern?

Now that a doctor is being prosecuted for his treatment of a patient, the question arises: What would it take for future malpractice allegations to be criminalized?

Leonard A. Simon, a solo practitioner in

Waltham who represents plaintiffs in medical cases, says the allegations in this case go far beyond a typical medical negligence case.

"If this is all true, it poses an awful danger to anybody else who walks into that office," he says. "This person is doing something which could almost be considered intentionally harmful to another person. ... This is a triple whammy."

Peter Heppner, a malpractice defense lawyer with Lynch & Lynch in South Easton, agrees.

He likens this scenario to a nursing home doctor who was prosecuted for homicide in another state for negligently using a dialysis tube as a feeding tube and then covering it up.

"It wasn't the initial error of judgment in the dialysis case but the cover-up afterward that caused the DA to prosecute," he says.

Regardless of how rare such a prosecution might be, other sources believe it could still cause discomf around Massachusetts doctors.

Bruce S. Auerbach, president of the Massachusetts Medical Society and chief of emergency and ambulatory services at Sturdy Memorial Hospital in Attleboro, says that since this is an ongoing matter and the specific details aren't clear, he can't comment on the case itself.

Hypothetically speaking, however, Auerbach says that criminally prosecuting a physician who is acting in what he believes to be the best interests of his patient "would not sit well with doctors."

Foster suggests that the occurrence of even a single high-profile prosecution could impact the way physicians practice, especially in high-risk specialties.

Some of the best medical outcomes occur because physicians and patients are willing

to take risks, he says. But a case like this could cause physicians to reconsider or even decline to offer a risky option.

Another worrisome issue is that a criminal prosecution wouldn't be covered by malpractice insurance, Foster notes.

"In fact, carriers in Massachusetts are prohibited by statute from providing insurance coverage for such conduct," he says.

## Political motivation?

Cirel believes there were political motivations behind the decision to prosecute his client.

"[My client] is a man who has written textbooks on performing this procedure, a man who has literally performed thousands of such procedures safely and in the same manner as this one," said Cirel. "Sometimes in medicine a bad outcome occurs. I think this one was criminalized because of the nature of the procedure, which is highly politicized."

Atto my Lee J. Dunn of Boston says he doesn't doubt Cirel's contention that the Osathanondh prosecution might be politically motivated.

"Abortion is still a white-hot issue and it wouldn't be the first time a DA has tried to pursue a case for his political benefit," says Dunn, who represents plaintiffs and defendants in med-mal cases.

If that's the case, it could create a disincentive for doctors to perform abortions, says Cirel.

But in general, the biggest threat to someone who performs abortions is not the county prosecutor, but "some clown on the front lawn with a hand grenade," says Dunn. MMLR

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# Good Medicine

What doctors are talking about now



**Q: Does the government's role in mandating medical services, either judicially or legislatively, negatively influence standards of care?**

"Absolutely. They have a lot of good intentions, but they're not working. We'll have better health care in Massachusetts if we allow the doctors to police themselves. The Massachusetts Medical Society is fine. Tribunals are fine. At this point in time, there should be one moral and ethical mandate: to provide universal health care. Any other regulatory interference with the doctor-patient relationship is negative. I don't tell lawyers how to practice law, or firefighters how to fight a fire. The U.S. has the resources and the ability to ensure that every sick person receives medical care. Beyond that, get out of my office."

— **Eric Ruby, M.D.**  
 Chief of Pediatrics, Morton Hospital and member of the Mass. chapter of the American Academy of Pediatrics

"In my experience, the state's role in mandating insurance coverage for medical services has had a significant positive impact on the availability of quality patient care. ... [W]e must be mindful that legislative mandates may affect premiums. ... There is also some concern that mandates for specific methods of treatment may become obsolete or be found ineffective as medical science and technology advance. ... Legislators should anticipate the eventual emergence of new technologies and advancements in patient care before approving any new mandate, and they should continue to regularly review existing mandates to ensure their compatibility with current standards of care."

— **Rep. Peter J. Koutoujian, D-Waltham**  
 Chair of the Joint Committee on Public Health

"I would hope that any legislation concerning mandates would always be driven by applicable medical standards of care, without provisions woven in that reduce patients' rights to legal recourse if they are victims of inappropriate care. If a piece of legislation results in substandard care due to a cost issue, that's a problem, particularly for those who cannot advocate for themselves, such as the elderly or the poor. The bottom line is no legislation should obviate the physician's responsibility to provide the appropriate standard of care. The patient's right to that care is sacrosanct."

— **Annette Gonthier-Kiely**  
 Medical malpractice attorney, Salem

"There are occasions where the government's efforts to regulate the provision of medical services, including the manner by which individual physicians provide that care, have had a significant deleterious impact on the quality of care provided. My recent experience with some of the policies of the Board of Registration in Medicine speaks loudly to the effect of intrusive regulation on the maintenance of appropriate standards. Professional staff members of the board had created such a hostile environment between licensed practitioners, the government, hospitals and patients that there were a growing number of highly qualified Massachusetts physicians who periodically considered, or decided on, relocating to other jurisdictions. Recent changes in the composition of the Board hopefully will lead to the establishment of a more productive environment."

— **Paul Gitlin**  
 Attorney, Rubin & Rudman, Boston, former chair of the Board of Registration in Medicine



## Mandated care requires a careful balancing act

By **Carole Allen, M.D.**

Physicians and other health care providers are operating under an increasing number of restraints, guidelines, regulations and laws.

These "mandates" are coming from multiple sources: state and federal governments, the courts, insurance companies, regulatory agencies and independent health care organizations that accredit and certify facilities and programs.

The motives behind these mandates are varied and generally valid: containing rapidly rising health care costs, reducing medical errors, providing for legal redress when errors may occur, protecting the public health and ensuring patient safety.

Oversight in the practice of medicine is certainly warranted and needed, but each mandate has a consequence, some unintended, whether for the practice of medicine, the doctor-patient relationship or in some cases, the costs to our health care system.

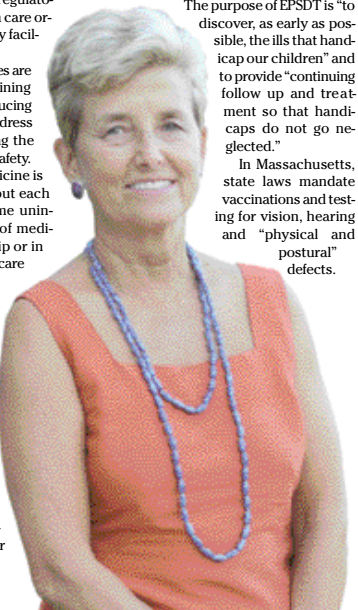
The proliferation of mandates raises some key questions: How do these requirements affect the physician-patient relationship? Do they ever conflict with clinical standards of care? Does the increasing time and administrative work physicians spend on mandates detract from the quality of care? Are we micro-managing our providers in the delivery of health care? And are we unwittingly spending more money than we should by duplicating care or providing care that's not indicated for patients?

Pediatricians perhaps see more of these mandates because their patients are children.

The U.S. Department of Health and Human Services has since 1967 required EPSDT – Early Periodic Screening Detection and Treatment – a program to address the physical, mental and developmental needs of low-income children under Medicaid.

The purpose of EPSDT is "to discover, as early as possible, the ills that handicap our children" and to provide "continuing follow up and treatment so that handicaps do not go neglected."

In Massachusetts, state laws mandate vaccinations and testing for vision, hearing and "physical and postural" defects.



Behavioral and mental health screenings are also now mandated by multiple directives.

The case of *Rosie D. v. Romney*, decided in 2006 in federal court, and more recently, a mental health omnibus bill called Yolanda's Law, passed by the legislature this year, create mandates for behavioral and mental health screenings that will affect how physicians, schools and hospitals care for hundreds of thousands of children up to age 21.

The EPSDT and Massachusetts goals are noble and important.

Some mandates, however, are less well-defined. Though not yet required in Massachusetts, a recent example is state-mandated "culturally competent care."

Now existing in a handful of states, this requirement addresses the growing ethnic diversity of the nation and tries to ensure that providers are trained in "cultural competency."

In California, the law goes so far as to require an element of cultural and linguistic competency in every Continuing Medical Education course. In New Jersey and New Mexico, medical schools must provide such instruction as a condition for the M.D. degree.

Specifics are still in flux, and states are treading carefully in deciding how they'll quantify and define this "care" and judge whether the mandate has been met.

Mandates are not inherently bad. I make this distinction: Those that protect and enhance the public or individual health (vaccinations for school children, for example) are good; those that hinder the practice of medicine (excessive documentation to sup-

port an imaging test a physician believes is necessary) are not.

Further, mandates that cause duplication of services, such as pediatric tests for scoliosis by both pediatricians and schools, may be inappropriate and wasteful.

Imposed care can also create disproportionate burdens on small or solo medical practices, particularly if such mandates are unfunded, putting added financial pressures on medical practices.

Mandates can also significantly raise the cost of health care and have the unintended consequence of creating disparities in care, for example, between children covered under EPSDT and those who are privately insured and hence not mandated for screening.

Mandated health care can be prudent and effective, filling critical gaps in care and providing care for those who wouldn't normally receive care. It can also be an impediment, duplicative and wasteful.

In essence, mandated care is a balancing act, especially as health care costs rise relentlessly. It is incumbent on those who have the power to create such requirements to ensure as much as possible – before mandates are issued – that quality of care is improved, that a need is filled that isn't otherwise addressed, that no additional burdens are placed on the provider and that the means to pay for such care is available.

**MMLR**  
 Carole Allen, M.D., specialty director for pediatricians at Harvard Vanguard Medical Associates, is president of the Massachusetts Chapter of the American Academy of Pediatrics.



# Online health records: new frontier in a 'wild, wild West'

By Sylvia Hsieh

The new online health accounts that give consumers a way to store and keep track of their medical data are the newest frontier in the unregulated terrain of electronic health records.

While laws like the Health Insurance Portability and Accountability Act (HIPAA) provide certain protections for records, online health accounts fall outside those regulations because the commercial entities offering them – Google, Microsoft, WebMD and Revolution Health to name a few – are not “health care providers,” nor does the data necessarily fall under the definition of a “medical record.”

This new form of online health record is part of a murky legal area with few laws, regulations or ethical constraints.

“It’s the wild, wild West in terms of people’s medical privacy,” said Tim Sparapani, senior legislative counsel with the American Civil Liberties Union in Washington, D.C.

The law is lagging far behind technology. “Microsoft HealthVault is live. Google Health is live. Revolution Health is live. The genie is way, way out of the bottle,” said Pam Dixon, executive director of the World Privacy Forum in San Diego.

Depending on the privacy policy of the health account vendor, consumers who have signed up for online accounts may have already given up certain protections, such as the doctor-patient privilege.

Patients are more likely to be asked if they have subscribed to an online health account by lawyers representing them, said Robert Gellman, an attorney and privacy consultant in Washington D.C.

“If I’m a litigator, the first question I would ask the patient is ‘Have you given your medical records to a PHR [personal health records] vendor?’ You can be sure someone is going to argue that the patient has waived the privilege by turning them over to a vendor,” he said.

## Not a HIPAA entity

The idea behind online health accounts is to let consumers manage their own medical records, much like managing personal photos through an online account.

For example, Microsoft’s HealthVault lets users manually upload medical information into their account and permits their health care practitioners to import data, including scanned images, into their account, said Elisabeth Giammona, a Microsoft spokesperson.

But the sensitivity of health data and the value of the personal information contained in a health record to an advertiser, data miner or lawyer makes it an area in need of greater oversight and regulation, privacy experts say.



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“When it comes to health records, we need something better than ‘buyer beware,’” said Deven McGraw, director of the health privacy project at the Center for Democracy and Technology in Washington, D.C.

“The main problem is that HIPAA doesn’t apply to Microsoft and Google, and we think there needs to be a comprehensive approach to privacy,” said Marc Rotenberg, executive director of the Electronic Privacy Information Center in Washington, D.C. and a privacy law professor at Georgetown Law School.

Online vendors of personal health records don’t fall under HIPAA because it is limited to health care entities and medical records held by a health care provider, said Gellman.

“Information can easily leak out of your health records,” he said, although he noted that if an online account is provided through a health care provider, it may be covered by HIPAA.

“A number of things change when records are held” by entities not covered by HIPAA, said Dixon.

She noted that HIPAA requires notification and the opportunity to object, seek a protective order and contest a subpoena of an individual’s medical records.

“We all know health records are often used in med-mal, tort and even custody and divorce cases. This is a big deal when you’re being sued, but I’m not convinced the average consumer has a full grasp of what it means to give up those rights,” Dixon said.

Even if HIPAA were to apply, it would not address privacy concerns, some experts say. “HIPAA is based on a business model driven by health care; Internet vendors operate on an ad-driven business model,” said McGraw.

## Privacy policies rule

Given the legal vacuum, the controlling law is the privacy policies promulgated by the Internet health records providers.

“Microsoft, Google, WebMD, and Revolution Health all have different privacy policies,” said Dixon.

But Gellman said “they all say ‘subject to change without notice at any time,’ so whatever promises have been made can be changed by them.”

Many privacy experts said the Internet vendors are making a good effort to address privacy concerns in their policies.

“We think Microsoft in particular is doing a good job on privacy, consent and giving patients the ability to control their records. Right now it seems to be the gold standard and Google is competing,” said Sparapani.


However, a big concern is how such privacy policies treat third-party applications made available to consumers through the online vendor. An example would be a diabetes management application that contracts with Google to allow GoogleHealth users to track their condition.

“Are the Googles and Microsofts requiring third parties to have privacy policies? At some point, the number of third-party applications will reach a point that they can’t guarantee they are policing those agreements,” said McGraw.

Peel’s organization is working on a credentialing system to rate the privacy policies of online health account vendors.

Such a certification process would require

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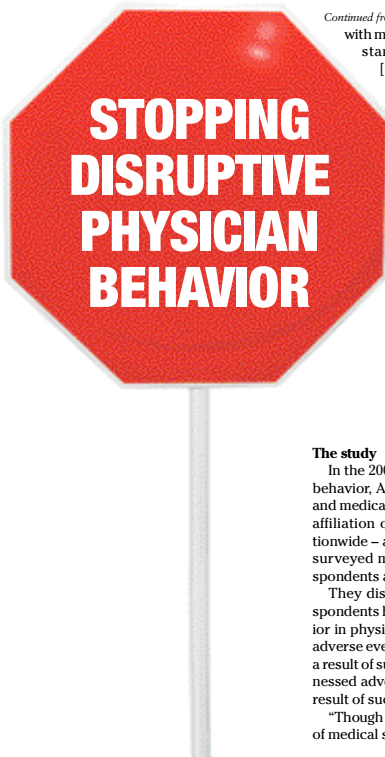
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*Continued from page 1*

with mental health, behavioral and substance abuse issues. "Enforcing [rules] against bad behavior is no fun, but it must be done to promote good behavior."

Experts suggest that organizations take steps to ensure that their conduct codes are effective by:

- Training medical staff on behavior in the health care workplace;
- Instituting an effective reporting procedure;
- Intervening in a supportive, non-punitive way; and
- Not using the code to discipline physicians for freely debating ideas about patient care.

**The study**

In the 2006 study of disruptive physician behavior, Alan Rosenstein – vice president and medical director of VHA West Coast, an affiliation of 1600 nonprofit hospitals nationwide – and co-author Michelle O'Daniel surveyed more than 5,000 anonymous respondents at more than 150 hospitals.

They discovered that 75 percent of respondents had witnessed disruptive behavior in physicians, 38 percent were aware of adverse events that could have occurred as a result of such behavior and 14 percent witnessed adverse events that were the direct result of such behavior.

"Though we found that only 3 to 5 percent of medical staff engage in disruptive behav-

ior, this small percentage has an enormous impact on the entire organization," says Rosenstein, a practicing internist who's observed such conduct in the workplace.

Meanwhile, a 2003 study conducted by the Institute for Safe Medication Practices revealed that 40 percent of clinicians have remained silent while witnessing such behavior rather than question an intimidating colleague.

Both sets of findings indicate that disruptive and intimidating physician behavior poses far greater risk to clinical collaboration and patient safety than most people realized, leading to the new standard.

**The scope of the problem**

A "Sentinel Event Alert" that accompanied the standard defines disruptive behavior to include verbal outbursts, physical threats, refusal to perform assigned tasks or respond to pages and phone calls, use of condescending language and impatience with questions.

Physicians agree that the number one cause of this behavior among their ranks is stress. The typical doctor has too much to do with too little time and overly high expectations to meet. Plus, many are dealing with life-or-death situations. Meanwhile, tensions are exacerbated by nursing shortages and grueling productivity requirements in the managed-care environment.

These tensions can make physicians angry, leading to disruptive behavior – and potentially negative consequences.

For example, a hospital could find itself mired in harassment, discrimination or hostile-work-environment litigation if it were to consistently allow physicians' abusive or demeaning behavior toward colleagues or

subordinates to go unaddressed, says health care attorney Jim Hilliard of Connor & Hilliard in Walpole.

Disruptive behavior gets particularly serious when it occurs in patients' presence, says Hilliard.

It can raise the anxiety level of patients who are already on edge. When it happens in psychiatric settings, where patients may be dealing with post-traumatic stress, it can cause them to experience the same sensations that drove them into the hospital in the first place.

"When it becomes an issue between clinical staff, patients feel like, 'My God, I'm a third wheel here,'" he says.

**Dealing with the problem**

No-rhod attorney Scott Liebert recalls an incident 15 years ago where a surgeon called in an anesthesiologist who was at home to perform a surgery that the anesthesiologist felt could wait until the morning.

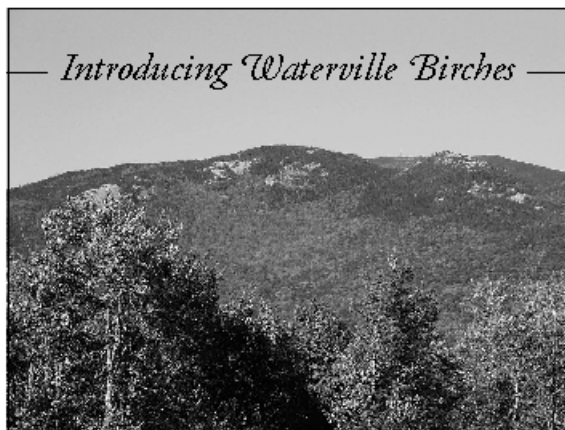
They verbally sparred in the patient's presence as the operating room was being set up, and once the patient was under anesthesia, the two started physically fighting.

"They were rolling on the floor in the OR," says Liebert. "Cooler heads in the room prevailed and they completed the case. The patient was never aware. But still the hospital took formal action and reported it to the Board of Registration in Medicine."

The fact is, as Rosenstein points out, hospitals have historically been reluctant to confront such situations head-on for a variety of reasons, perhaps most significantly the hierarchical nature of the hospital.

It's natural that a hospital administrator will be hesitant to confront a prominent sur-

*Continued on page 11*



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geon who produces a huge amount of revenue for the hospital about his abusive or intimidating demeanor, but it may need to be done for the sake of patient safety.

The inability of hospitals to police themselves is exactly what spurred the Joint Commission to act. But experts stress that the standard is very open-ended and any behavior policy will have little impact without certain steps being taken.

Mary Anne Badaracco, chief of psychiatry and chair of the medical executive committee at Beth Israel-Deaconess Medical Center in Boston, says medical staff at her hospital undergo constant training in acceptable professional behavior.

"All our departments are expected to have as part of their regular education meetings guidelines about physician behavior and health and how to approach a physician who we think is having difficulty," she says.

## Tips for physician behavior policies

- Train medical staff on behavior.
- Institute an effective reporting procedure.
- Intervene in a supportive, non-punitive way.
- Do not use the code to discipline physicians for debating ideas about patient care.

However, a behavior code is useless if people don't know to whom to report an inci-

dent or, worse yet, fear retaliation or feel doing so will be futile, says Rosenstein.

"We recommend a consistent process of handling every single complaint, and maybe even a multidisciplinary group to review every complaint," he says.

At the same time, he adds, "people need to change the attitude of, 'I can't do this to this physician.' The CEO instead needs to say, 'I can't tolerate this.'"

### Supportive manner

Liebert says interventions need to be handled in a supportive manner rather than a punitive one.

If all a hospital does is punish, it creates an environment where people may be even more afraid to come forward with a complaint out of fear of getting someone powerful in trouble.

Instead, he suggests carefully investigating the situation. Perhaps a doctor is acting

out because of an anxiety disorder that's inadequately diagnosed, or a substance abuse problem.

"In a lot of situations, intervention early on can be in everybody's best interest," Liebert says, adding that referring a troubled physician to PHS, Sanchez's organization, for assistance is often an excellent first step.

Finally, hospitals must ensure that their code is used appropriately to protect patient and staff safety.

"When evaluating disruptive behaviors we would hope that the process is done fairly and conclusions are based on a thorough, unbiased review of the situation with resulting actions based on the merits of the situation and not the individual involved," Rosenstein says.

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# Online health records: new frontier in a 'wild, wild West'

Continued from page 9

that the privacy policy make a clear statement of consumer control and that the vendor subject itself to an outside audit to make sure it is abiding by its policy.

But Dixon said even the best privacy policy cannot make up for holes in the legal framework, such as a waiver of the doctor-patient privilege by uploading your records to a site.

"Doctor-patient privilege is a very significant privacy protection. Once data is moved and consent is signed, you've waived your privilege. It's evaporated. Gone," said Dixon.

### Pending legislation

Although there are two pending bills in Congress that promote electronic records and call for recommendations on regulations from

the Department of Health and Human Services on privacy and security of electronic patient records, neither bill would create a private cause of action for individuals whose health records are disclosed without consent.

"The bottom line is none of these bills is good. There needs to be a private cause of action and robust privacy and security provisions," said Dixon.

The bills are: The PRO(TECH)T Act of 2008 ("The Protecting Records, Optimizing Treatment, and Easing Communications through Healthcare Technology Act"), H.R. 6357, and the Wired for Healthcare Quality Act, S. 1418.

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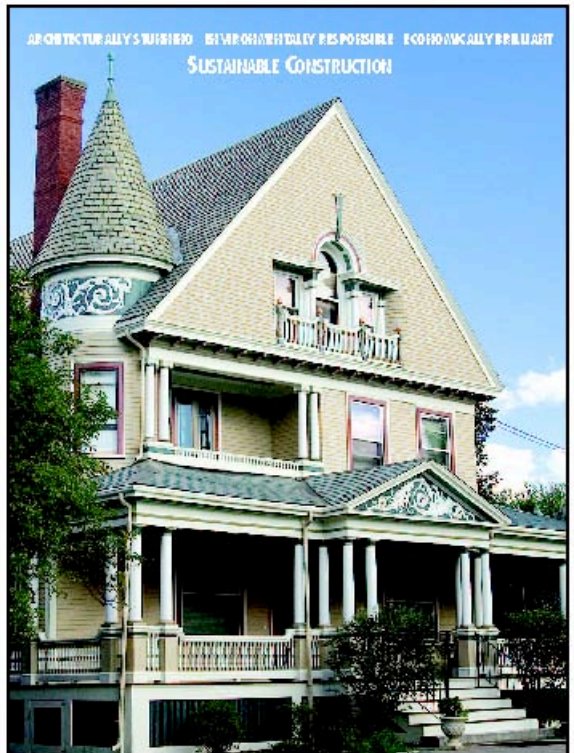
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## From Beacon Hill

### Patrick OKs limits on gifts to doctors

Gov. Deval L. Patrick signed into law one of the nation's strictest limits on gifts given to medical professionals by drug salespeople, the most contentious measure contained in a broad package intended to improve health care safety and curb costs, according to the Boston Globe.

The law, based on a plan pushed by Senate President Therese Murray, D-Plymouth, also seeks to increase the number of primary care doctors in the state.

The new law provides \$25 million to promote the use of electronic medical records in physicians' offices.

It also requires the University of Massachusetts Medical School in Worcester to increase its class size with the intention of having more primary care doctors graduate and gives regulators the power to hold hearings when health insurers want to raise premiums.

Critics of the pharmaceutical industry had hoped gift-giving would be banned altogether. They argue that gifts from pharmaceutical companies interfere with physicians' decisions about which drugs to prescribe.

But the final version bans only certain types of gifts, including sports tickets and free travel, and requires that pharmaceutical and medical device firms publicly disclose gifts worth more than \$50, the Globe reported.

### Hospitals' ability to expand into suburbs is curbed

State health regulators made it significantly harder for Boston's teaching hospitals to expand into the suburbs, a move designed to protect smaller community hospitals that feel under siege from their powerful rivals, according to the Boston Globe.

The measure drafted by the Patrick administration, which won support from the Public Health Council, will force hospitals to prove that proposed expansions do not duplicate services. Until now, hospitals hoping to add overnight beds at outpatient facilities faced little scrutiny from the state.

Community hospital administrators have watched with increasing alarm as hospitals affiliated with Harvard and other universities, such as Massachusetts General Hospital, Beth Israel Deaconess Medical Center and Tufts Medical Center, extended their reach into the suburbs.

The satellite campuses, along Route 128 and other corridors, have focused mainly on outpatient services, ranging from high-tech care to more basic treatment that is the bread and butter of local hospitals, the Globe reported.

Those concerns reached a pitch when the region's premier pediatric teaching hospital, Children's Hospital Boston, added 11 inpatient beds last year at its outpost in Waltham, an expansion that required only nominal state review.

State leaders also have their own reasons for being troubled by the arrival of teaching hospitals in the suburbs: economics.

As Massachusetts becomes the first state to provide health insurance to nearly every resident, state government is picking up much of the tab for more than 300,000 newly insured residents.

Health regulators warn that if those patients flock to academic centers for care, it could substantially increase the state's costs, without necessarily improving how patients fare. Studies have shown that the higher costs of teaching hospitals do not uniformly translate into better health care, especially for routine services.

The change in state regulations governing expansions could prove to be a signal, and unusual, triumph for community hospitals, according to the Globe.

### Health care strategy blasted by employers

Calling it the "wrong approach," the state's largest employer and insurer groups told legislative leaders that Gov. Deval L. Patrick's new effort to raise \$130 million to fund state health care costs by asking employers to pay more fails to address factors fueling rising costs, adds costs for businesses already saddled with rising insurance premiums and may lead to a "permanent tax."

In a letter to House Speaker Salvatore F. DiMasi, D-Boston, and Senate President Therese Murray, D-Plymouth, employers and insurers call for no action on the plan that Patrick says is necessary to help the state cover growing costs associated with its 2006 law expanding access to health care and health insurance.

The governor's proposal is pending in a spending bill before the House Ways and Means Committee.

The letter was signed by the heads of 23 business groups and employers, including the Greater Boston Chamber of Commerce, the Small Business Service Bureau Inc. and the Massachusetts Association of Health Plans.

The Patrick administration, dealing with extended talks with the federal government over health care funding, is looking to extract \$130 million from employers, health insurers, health care providers and taxpayers to pay for care to low-income residents in a "continued spirit of shared responsibility."

### State purchasers won't pay for medical errors

State health insurance purchasers will no longer pay for costs associated with surgery on the wrong body part or wrong patient, or a patient death or serious disability that resulted from a medical error.

The policy, in which agencies will no longer allow providers to bill members for services associated with such errors, was adopted by four state agencies that collectively insure or purchase care for 1.6 million residents. They include the Office of Medicaid, the Group Insurance Commission, the Health Insurance Connector Authority and the Department of Correction.

"By adopting a consistent policy, Massachusetts is applying the state's purchasing power in support of patient safety," said Health and Human Services Secretary Judy Ann Bigby. The policy will be implemented at the start of the next contract cycle for each agency, according to the secretariat.

The state Department of Public Health requires hospitals to report serious incidents classified as "reportable events," including surgery on the wrong patient or an infant discharged to the wrong person.



## From Capitol Hill

### Performance plan shows improved care, savings

CMS reported that a pilot program paying physicians based on quality and efficiency of care has shown gains in quality of care and in some cases lowered costs, CQ HealthBeat reports.

In the second year of the four-year Physician Group Practice demonstration project, all 10 groups participating improved quality of care to patients with congestive heart failure, coronary artery disease and diabetes, CMS reported. Four of the groups also reduced the cost of care to patients and reduced CMS spending by \$17.4 million. Physicians participating in the project said the success could be attributed to their use of teams that include different types of doctors to provide the right amount of care at the right time to chronically ill patients.

Barbara Walters, senior medical director of the Dartmouth-Hitchcock Medical Center, said her health system saw some of the most medically complicated cases in its geographic area but still was able to save funds.

She added that electronic health records played a critical role in allowing the multidisciplinary team to coordinate services.

Other participants said they used a "visit planner" to create "to-do" lists for physicians prior to each patient's visit.

In all, participating physicians received \$16.7 million in incentive payments. According to a CMS release, the four groups that lowered costs "earned \$13.8 million in performance payments for improving the quality and cost efficiency of care as their share of a total of \$17.4 million" in Medicare savings they generated.

### Asthma, pneumonia data added to Medicare site

Medicare, coupled with the Hospital Quality Alliance and other stakeholders, has updated the Hospital Compare website to include pneumonia mortality rates and treatment statistics for young asthma patients—a move intended to help patients better rate and compare hospitals, according to the Health IT Strategist newsletter.

This is the second update to the site this year. In March, CMS added patient-satisfaction data to the already existing 39 quality measures it tallies and ranks.

With the addition of the pneumonia mortality information, the website now houses mortality data for three common medical conditions, including heart attack and heart failure.

Going back to last year, Medicare has seen improvement nationally on mortality rates for heart attacks, dropping to 16.1 percent reported this year from 16.3 percent from 2007.

The update to the website, postponed from its scheduled mid-July debut, also allows consumers to get a better handle on the data that hospitals report.

While it used to include whether a hospital was better than, the same or worse than the national average, patients can now see risk-adjusted data, including the number of cases for each hospital.

The Hospital Quality Alliance is a voluntary public-private initiative that includes hospitals, physicians, nurses, federal agencies, quality experts, consumer and business groups.

### Doctors: Lawsuits help to ensure drug safety

Top physicians who run one of the most influential U.S. medical journals are giving the U.S. Supreme Court some legal advice about a major case.

Lawsuits can serve as "a vital deterrent" and protect consumers if drug companies do not disclose risks to the Food and Drug Administration before it approves medicines for use, the editors of the *New England Journal of Medicine* said in a friend-of-the-court brief. The FDA "is in no position" to guarantee drug safety, the brief said.

At issue is *Wyeth v. Levine*, a case expected to be heard late this year that could have far-reaching implications for litigation over allegedly harmful drugs, such as the painkiller Vioxx.

In the case, Diana Levine, a Vermont guitarist, lost her right arm below the elbow after she was injected with Phenergan, a medicine for nausea, and developed gangrene.

She sued the manufacturer, Wyeth, arguing that the company had neglected its duty to warn consumers that such injections could have devastating consequences.

The courts in her state agreed, awarding her almost \$7 million.

But Wyeth appealed, countering that it was protected from such lawsuits.

It argued that the FDA regulatory judgment could not, in effect, be overruled by a state court. FDA scientists had weighed the risks and benefits of Phenergan in approving the drug's label.

The FDA was aware of risks associated with injecting some forms of Phenergan, but the label did not specifically warn about the technique used with Levine.

The journal's editor, Dr. Jeffrey M. Darien, said in an interview that he hoped arguments over legal distinctions will not obscure the reality that the FDA is overwhelmed trying to keep up with drug safety problems, which can range from rare but serious side effects to shortcomings in manufacturing plants as far away as China.

"Even if the FDA is doing the best it can, it simply can't see the future clearly enough to preempt manufacturers from litigation," he said. "The [court] system represents one of the key defense mechanisms that individuals have if a manufacturer has not made the risks of a product clear to the public."

The medical editors joined 47 state attorneys general and two former FDA commissioners, David Kestrel and Donald Kennedy, in supporting Levine's position. Kestrel served in the administrations of former Presidents Bill Clinton and George H.W. Bush. Kennedy served in President Jimmy Carter's administration.

The case is being closely watched because the Supreme Court ruled this year that manufacturers of FDA-approved medical devices were shielded from litigation in state courts.

However, David Vladeck, a lawyer representing Kessler and Kennedy, said the statute that applies to medical devices is different from the law that governs medications.

"The law in the [devices] case had a pre-emption provision," which means state law claims would be barred, said Vladeck. "Congress has never put a pre-emption provision in the Food and Drug Act."

The Bush administration is supporting Wyeth's position.

# Earn CME Credits

## How to e-mail patients without worrying about liability

<b>Original Publish Date:</b>	9/16/08
<b>Review Date:</b>	NA
<b>Estimated Time to Complete:</b>	1 Hour
<b>Term of Approval End Date:</b>	9/16/09
<b>Risk Management:</b>	Yes
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### Course Information

#### Intended Audience

This course is intended for physicians and allied health professionals.

#### Course Objectives

- Describe examples of successful physician-patient e-mail communication used in other physician practices.
- Explain how the HIPAA privacy and security requirements impact e-mail communication with patients.
- Understand how communicating via e-mail may protect your practice.
- Identify processes and procedures for implementing patient e-mail communication in your practice.

#### Course Credit

The Massachusetts Medical Society designates *E-mailing Patients Without Worrying About Liability* for a maximum of 1 *AMA PRA Category 1 Credit™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This program meets the criteria of the Massachusetts Board of Registration in Medicine for risk management study.

Participants will receive a confidential report of their examination score. You must receive a score of 70% or better to receive *AMA PRA Category 1 Credit™*. A confirmation of credit will be issued at the end of the course to those who successfully complete the examination.

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#### Bibliography

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#### By Reni Gertner

As more and more doctors use e-mail to communicate with their patients, their lawyers are jumping in to help them establish policies and procedures to avoid having the practice land them in legal hot water.

From concerns about being sued for medical malpractice for missing key illness details to fears of breaching the confidentiality of patients' electronic health information, using e-mail to communicate with patients without following proper guidelines could become a physician's legal nightmare.

However, by establishing clear procedures, doctors can communicate with patients electronically while minimizing the risk of being sued.

"If the medical practice is saying this is something they want to do to make their business be more user-friendly, the goal should be to facilitate that while making sure patients' expectations are appropriately set," says Boston attorney David Szabo, co-chair of the healthcare group at Nutter McClennen & Fish.

Lancaster, Pa., attorney Jim Saxton, who practices at Stevens & Lee, agrees.

"It's here," says Saxton, who represents medical professionals and hospitals and has written books about proactive risk management. "I don't think we can afford to say, 'There might be liability exposure, so we're not going to do it.'"

In fact, some experts contend that using e-mail may even help doctors reduce the risk of being sued.

"Used wisely and well e-mail can reduce your malpractice liability," asserts Dr. Daniel Sands, an internist at Beth Israel Deaconess Hospital in Boston and the Senior Medical Informatics Director of the Internet Business Solutions Group at Cisco Systems.

Sands believes that using e-mail can lower the risk of litigation by "reducing barriers to doctor-pa-

tient communication" allowing "self-documenting" of physician-patient interactions. Approximately 10 percent of med-mal lawsuits won by patients stem from the doctor's lack of documentation in the record, he notes.

#### Balancing risks and benefits

Attorneys say that physicians need to pay attention to both federal and state law in order to reduce their legal risks when communicating with patients by e-mail.

From a medical malpractice standpoint, one of the biggest fears is being sued under state law for missing a symptom or diagnosis based on e-mail interactions – or missing an urgent e-mail message altogether.

Another major area of concern is complying with the patient privacy and health information security requirements of HIPAA, the federal Health Insurance Portability and Accountability Act.

Under the Act's privacy rules, only a patient or the federal government can "require" disclosure of the patient's protected health information. The patient can also request the format in which he or she would like the information to be disclosed, including in electronic form. The health care provider must then produce the information in the requested format, as long as it is "readily producible."

The HIPAA security rule, which covers electronic health information, states that the protection of this information while in transit is an "addressable" concern that a covered provider should deal with based on its own risk analysis.

According to Sands, "HIPAA suggests it's a good idea to encrypt communications on the Internet," but gives providers leeway on whether to do so and how to go about it.

The rules an entity follows might differ based on who is receiving the information and how it is being sent.

## Doctor-patient e-mail

### in practice: Policies

#### and procedures

Here are some policies and procedures that physicians should consider when using e-mail with their patients:

#### • Outline permissible uses.

With an array of legal problems that can arise, some attorneys recommend that their doctor clients use e-mail with patients only on an extremely limited basis.

For example, administrative uses such as scheduling appointments or sending test results are "pretty low-risk and straightforward," says Saliha Khaja Greff, who practices health law with Caplan and Earnest in Boulder, Colo. Melissa Jackson, an attorney with Blackwell Sanders Peper Martin in St. Louis, says she advises clients to limit e-mail with patients to strictly administrative uses.

"We provide fairly conservative advice to our doctors," she says.

"While e-mail is a good tool, I would not really get into the medical information at all."

But others say e-mailing patients about their care – including giving basic medical advice – is becoming an inevitable part of doing business in some parts of the country, and what really matters is how you go about it.

While some physicians will use e-mail purely for administrative purposes, other doctors might allow patients to ask general questions about their upcoming treatments or procedures or to ask for a prescription refill, says Lancaster, Pa., attorney Jim Saxton. Or "a patient might send an e-mail to a nurse educator to review the risks and requirements after surgery," says Saxton, who represents medical professionals and hospitals and has written books about proactive risk management. And some clients may allow patients to actually ask medical questions about symptoms and illnesses.

But there is one thing all attorneys and physicians agree on: If a question is "time sensitive or medically urgent, it should never be sent through electronic communi-

One key aspect of complying with HIPAA, says Atlanta attorney Barry Herrin, is to document your analysis of the risks and benefits and explain any security choices you make.

Essentially, you have to "show your work," says Herrin, who specializes in HIPAA concerns and health care compliance at Smith Moore.

These privacy, confidentiality and security concerns can also be an issue under state laws on privacy and medical records.

But as long as physicians and their lawyers take these issues into account, email interaction with patients could reduce liability by increasing communication – which has been shown in some studies to cut the number of med-mal suits.

E-mail is a convenient way for "patients to say, 'Can you explain again exactly what I am supposed to be doing?'" says Saliha Khaja Greff, who practices health law with Caplan and Earnest in Boulder, Colo.

Sands says he frequently uses e-mail in this way, and it tends to improve patient satisfaction and outcomes, both of which reduce litigation.

"If patients have a question after I've hung up the phone with them, they are not going to try to call me back," he said. "In e-mail, I routinely send a patient a message with links to supplementary information, which ultimately leads to better outcomes."

Dr. Ann Loudermilk, an emergency physician in Boston, says she has used e-mail as a patient in exactly that way. "It's such an easy way to get a hold of your doctor," she says.

And from a risk management perspective, a major plus of e-mail is that it "creates an automatic paper trail," notes Greff. **MMLR**

Questions or comments can be directed to the writer at: [reni.gertner@mamedical.com](mailto:reni.gertner@mamedical.com)

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But there is one thing all attorneys and physicians agree on: If a question is "time sensitive or medically urgent, it should never be sent through electronic communication," says Dr. Daniel Sands, an internist at Beth Israel Deaconess Hospital in Boston and the Senior Medical Informatics Director of the Internet Business Solutions Group at Cisco Systems.

The length of time since the patient last saw the doctor for treatment should also be taken into account. "If the physician last saw the patient a year ago, I would advise a client not to issue a diagnosis over e-mail," says Greff. "The same symptoms can mimic any number of illnesses."

Whatever a physician practice decides, a written e-mail policy will make clear to patients what they can expect. Physicians should have patients "sign an informed consent form on their use of Internet or e-mail services, which includes the permissible uses," recommends Greff. "Unless you say it to the patient, you're setting yourself up for legal trouble."

Such a policy might indicate that patients should call if they haven't heard back in two business days about a non-urgent matter, Sands says.

That "creates a lack of expectation" says Greff. **Continued on page 14**

## Doctor-patient e-mail in practice: Policies and procedures

Continued from page 13

tion for an immediate response," says Atlanta attorney Barry Herrin, who handles HIPAA and health care compliance at Smith Moore.

### • Implement a system.

One of the most important things physicians can do is make sure they keep the limitations of technology in mind. Doctors "can't be afraid to say, 'This doesn't feel right, you have to come in' or 'Let's talk on the phone,'" says Sands, who has written patient-doctor electronic communication guidelines for a number of organizations. "Just because a message comes in electronically doesn't mean you have to handle it electronically," Saxton agrees. "Anything that would need a clinical exam still does. When in doubt, you have to see the patient."

"E-mail should also be avoided when it comes to complicated test results. 'If the results are serious, the physician should call directly,'" suggests Maureen Mondor, vice president of risk management at ProMutual Group in Boston.

And just like phone messages,

any e-mail correspondence must make its way into the patient's medical record, whether in electronic format or printed out.

It also helps to have a mechanism to make sure any e-mails that are sent to a patient actually make it into his or her inbox, such as an automatic return receipt function.

In addition, doctors could "tee up their e-mail server to send back a message that says in an immediate response, 'If you think you're having an emergency situation, go to the ER or call 911,'" suggests Herrin.

Any doctor who is going to communicate with his or her patient by e-mail must make sure no medical information is sent to a work e-mail account.

"We strongly discourage any system that sends protected health information to an e-mail account controlled by an employer," says Boston attorney David Szabo, co-chair of the healthcare group at Nutter McLenen & Fish. "Your employer owns your computer and hard drive and you have no privacy rights against your employer."

It should also be clear who from the office is e-mailing the patient at

any given time.

To protect patient privacy, Greff suggests that doctors shouldn't have "e-mails to patients accessible to everyone in the office." Also, "If you choose to have someone else reading your e-mail, you have to be totally transparent about what's happening," says Sands. "You don't want someone saying he is Dr. Sands when he is not." He notes that it is a HIPAA violation to log in with someone else's name and password. If a physician won't have access to email for a defined period of time, lawyers recommend that he or she have an automated out-of-office message.

### • Guard privacy/security of patient health information.

One way to make e-mail communication with patients more secure is for physicians to use software to encrypt the e-mail they send.

Sands says that individuals can use software as simple as Microsoft Outlook to encrypt outgoing e-mail. ZixCorp, where Sands used to work, provides encryption systems for larger institutions and groups.

While encrypting e-mail is a good idea, it's not required by HIPAA, says Herrin.

"Under HIPAA, you don't have to encrypt your e-mail as long as you address the security concerns you have in your risk management profile," he says.

Sands suggests that "if you want to use regular unencrypted e-mail, you should have a policy that says why you're not using encrypted e-mail."

"Another option is to have all e-mail sent through a secure communication portal. With a set up like that, 'you log into a secure website and send your communication. When a doctor or patient has a message, he gets an e-mail saying 'You have a message waiting for you on the site,' and it stays on this secure server," says Sands.

Relay Health, an Emeryville, Calif.-based company, provides such a system.

According to the company's chief operating officer, Ken Tarkoff, one of the best features is that the system is set up and controlled by the doctor and the patient, and they can disconnect at any time.

Also, it allows the doctor to make sure he or she doesn't "receive medical messages from a non-established patient," says Tarkoff.

In addition, Relay Health ensures that all of its products are HIPAA-compliant. "We are not a covered entity, but all of our customers are, so we need to supply something that is HIPAA-compliant," says Tarkoff.

Another strategy for ensuring HIPAA compliance is to get consent from the patient to send the health information you are sending in the manner you will be sending it.

For example, an agreement might say: "When you send information to us, it's not going to be encrypted," Herrin suggests. "The key is getting patient permission so they can make a knowing and voluntary waiver of any privacy rules." No matter what electronic system a physician uses, there are certain sensitive areas that should generally be kept out of e-mail, including HIV, sexually-transmitted diseases, substance abuse and domestic violence. Even if it's not "a problem from a privacy standpoint [because] it's secure or encrypted,

## The Physician's Corner

### Considering e-mail contact with patients?

By Henry Tulgan, M.D., FACP

Not so long ago, the thought of communicating with patients electronically would have caused most physicians to shake their heads.

Now it is estimated that up to one-third of medical practices use e-mail to communicate with their patients, and more are investigating moving in this direction.

However, there are a number of federal and state laws to review before taking this step. To prevent medical malpractice and prevent potential loss, the following concerns should be addressed.

Two of the most pressing areas for physicians to consider are the possibility of missing a symptom or diagnosis due to lack of an on-site presence, or missing an urgent patient message due to an overburdened inbox.

Realistically, patients who have not been seen directly in a practice setting for lengthy periods are not appropriate candidates for an on-line consultation. An in-person visit should be scheduled, with only follow-up communications allowed via e-mail. Starting with an office visit will enhance the patient's re-

lationship with you and will reduce your potential liability.

### Privacy and security

On the federal level, the Health Insurance Portability and Accountability Act (HIPAA) requires that you limit employee access to specific programs of an electronic system or patient database.

HIPAA suggests the use of encrypted messages, but there currently remains a dearth of parameters as to what are considered best practices.

Many states are also considering confidentiality and security legislation related to electronic medical records.

Therefore, practices should conduct a risk-benefit analysis to ensure that the benefit of patient communications via e-mail clearly outweighs the risk.

If you decide to use e-mail for patient contact, you should develop strict policies and procedures for its use, including defining who has access to the system and who does not.

The use of e-mail for appointment scheduling, for routine prescription refills and for reporting of customary test results is considered low risk.

However, revealing complicated or complex results, especially if they are serious and/or time-sensitive must be dealt with more directly. Attorneys and others with Internet security expertise and experience offer some advice. The best and safest practice for physician offices is to use encryption for e-mail with patients. Several commercial systems are available for physician offices.

Another option is to use a secure communication portal. Both ensure HIPAA compliance.

It is also strongly advised to obtain in writing a patient's permission to communicate via e-mail to document that he or she has decided voluntarily to waive privacy rules.

The written permission, as well as all electronic communication, must be included in some fashion in the permanent patient record. While still in early stages, several insurance carriers are embarking on pilot programs to compensate physicians who use Internet sites for "virtual house calls."

As current and future generations of patients and physicians are computer literate and as systems become more sophisticated, it is very likely that electronic com-

munications will be commonplace in physician practices.

However, the American Medical Association cautions that this mode of patient contact should not replace appropriate face-to-face interactions, the tried and true foundation of the doctor-patient relationship.

### Risk management strategies

- Outline permissible uses for e-mail in your practice (e.g. administrative uses such as scheduling).

- Have a written e-mail policy to clarify what patients can expect from physician-patient electronic communication.

- Implement a system in your practice that includes written physician-patient communication guidelines.

- Have patients sign an informed consent form on their use of Internet and e-mail services with your practice.

- Have all patient e-mails sent through a secure communication portal, encrypt outgoing e-mail or address security concerns in your risk management profile.

- Do not answer time-sensitive or medically urgent patient questions via e-mail. Choose direct communication and document the interaction.

Henry Tulgan, M.D., FACP, an advisor to the Committee on Sponsored Programs for the Massachusetts Medical Society, is a clinical professor of Medicine at the University of Massachusetts Medical School and a consultant.

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- HIPAA legislation mandates the use of encrypted e-mail messages to patients.
  - True
  - False
- The use of e-mail for patient scheduling and prescription refills is considered:
  - High risk
  - Moderate risk
  - Low risk
- Any individual in a medical practice may have access to e-mail systems.
  - True
  - False
- Electronic communications with patients:
  - a. should always be part of the permanent medical record.
  - b. should be a part of the permanent medical record when important.
  - c. may be discarded when the transaction is complete.
  - d. all of the above.

Please complete the evaluation portion of this activity. Your feedback is important in developing future educational programs. Please send additional comments to continuingeducation@mms.org.

Did this activity meet the stated objectives?

Yes  No

If yes, please explain.

How do you rank the effectiveness of this activity as it pertains to your practice?

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Yes  No

Did you perceive any evidence of bias for or against any commercial products?

Yes  No

What are your topics of interest for future CME activities?

# Doctor can be sued for patient's lost chance of survival

Continued from page 1

*Matsuyama v. Birnbaum*, was a wrongful death lawsuit brought by a widow claiming that her husband's lost chance of recovery resulted from a doctor's failure to treat his stomach cancer.

The physician argued that adopting this theory would result in a radical change in established law and constitute an impermissible judicial amendment to the wrongful death statute.

But the court disagreed, finding that the doctor could be sued for his failure to properly diagnose the patient's fatal stomach cancer and causing him to have a less than even chance of survival.

"Although we address the issue for the first time today, a substantial and growing majority of the states that have considered the question have [endorsed] the loss of chance doctrine, in one form or another, in medical malpractice actions," wrote Chief Justice Margaret H. Marshall for the court. "We join that majority to ensure that the fundamental aims and principles of our tort law remain fully applicable to the modern world of sophisticated medical diagnosis and treatment."

In a companion case, *Renzi v. Paredes*, the plaintiff claimed that a doctor's delayed diagnosis reduced the patient's likelihood of long-term survival and led to her death from inflammatory breast cancer.

The court held that loss of chance damages are recoverable where a physician's negligence reduced the decedent's chances of survival from a better than even chance to less than even.

## Doctors 'afraid'

As a result of the rulings, Boston med-mal defense attorney David Gould said that doctors are "afraid" because "they think it's difficult enough to deal with large numbers of patients, and now they feel the legal system is coming down harder and harder on them."

Bruce Auerbach, president of the Massachusetts Medical Society, contended that the diagnostic and "staging" levels for cancer, as alluded to in the decision, "were never intended for purposes of civil litigation. They were determined to help guide [physicians'] clinical evaluation and strategy."

If the ruling "stays out there unchallenged," he cautioned, it has the potential of limiting access to medical care.

"Physicians might start to limit their practices to those patients that have a better chance of a cure," said Auerbach, who is vice president of emergency and ambulatory services at Sturdy Memorial Hospital in Attleboro.

Still, "as long as physicians practice ap-



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**"Physicians might start to limit their practices to those patients that have a better chance of a cure."**

**— Bruce Auerbach**

propriately within the standard of care, they have nothing to worry about," said Gould, who practices with Ficksman Conley.

Joseph L. Doherty, of Boston's Doherty & Quill, whose practice consists primarily of defense work, predicted that there won't be an increase in claims against physicians as a result of the rulings.

"I don't anticipate that we're going to see a barrage ... of stand-alone loss of chance cases apart from the wrongful-death medical-malpractice claims that have always been allowed," he said.

But doctor-lawyer Max Borten, a partner at the law firm of Gorovitz & Borten in Waltham, who represented the executrix of the estate of the man who died of stomach cancer in the SJC case, said the court's ruling represents a dramatic change in the law by permitting a larger class of aggrieved patients to bring suit.

"The court is clearly saying that a doctor should not be absolved of negligence just because a patient had a less than 50 percent chance of survival or recovery," said Borten, who is a licensed obstetrician-gynecologist.

## Cancer cases

In the first case, the executrix of the patient's estate filed a wrongful death complaint in Superior Court in 2004 against the doctor who had treated her husband.

The complaint alleged that the patient presented with symptoms of gastric cancer in 1996, but that the doctor failed to properly diagnose and treat him.

The doctor saw the patient six times over four years. He always recommended over-the-counter antacids for the patient's stomach pain and he didn't order diagnostic tests until less than five months before the man's death.

It was then discovered that he had cancer over 70 percent of his stomach. He died of gastric cancer in October 1999.

At trial, an expert for the plaintiff testified that as a result of the doctor's breach of the standard of care, the patient lost the opportunity of having his gastric cancer "diagnosed and treated in a timely fashion when it might still have been curable."

The jury found the physician negligent in misdiagnosing the patient's condition. The jury also found the doctor's negligence was a "substantial contributing factor" in the patient's death.

As a result, the patient's widow and son were awarded \$328,125 for the loss of chance of survival. The SJC affirmed the award.

In the second case, the defendants argued that the breast cancer was a very aggressive form usually diagnosed at an advanced stage, and that due to the "biology" of the tumor the decedent's prognosis for survival was poor and "her fate was sealed."

But the court rejected the argument, affirming a \$2.8 million verdict.

## New doctrine

Despite the doctor's argument that the court's ruling would unfairly expand the causes of action available to plaintiffs in Massachusetts, Marshall said the decision was limited to med-mal cases.

"[T]he loss of chance doctrine views a person's prospects for surviving a serious medical condition as something of value, even if the possibility of recovery was less than even prior to the physician's tortious conduct," she wrote. "Where a physician's negligence reduces or eliminates the patient's prospects for achieving a more favorable medical outcome, the physician has harmed the patient and is liable for damages."

In a footnote, the judge noted that the highest courts of at least 20 states have already adopted the doctrine.

In any case involving loss of chance, Marshall explained, a plaintiff first has to establish by a preponderance of the evidence that a doctor's negligence caused the injury.

"Courts ... also have noted that, because a defendant's negligence effectively made it impossible to know whether the person would have achieved a more favorable outcome had he received the appropriate standard of care, it is particularly unjust to deny the person recovery for being unable to demonstrate to an absolute certainty what would have happened in circumstances that the wrongdoer did not allow to come to pass," she wrote.

Marshall said the doctrine originated out of dissatisfaction with the prevailing "all or nothing" rule, which allowed plaintiffs to recover only by showing that a physician's negligence more likely than not caused a patient's death.

As long as the patient's chance of survival before the physician's negligence was less than even, it was logically impossible, the judge wrote, to show that the patient would not have died without the doctor's allegedly negligent conduct.

Regardless of how flagrant the negligence, Marshall said, the "all or nothing" rule unfairly provided doctors a blanket release from liability any time there was less than a 50-percent chance of survival.

"In sum, whatever difficulties may attend recognizing loss of chance as an item of damages in a medical malpractice action, these difficulties are far outweighed by the strong reasons to adopt the doctrine," she said. **MMLR**

*Questions or comments should be directed to the writer at: david.frank@lawyersweek-ly.com*

# Medical credit cards

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tending credit to a patient, Wilner said that patients have complained that their medical providers are running credit checks to look for open lines of credit.

"The billing office will run the credit score and say to the patient, 'Oh, I see you have a Visa card and you have \$1,600 in available credit. Why don't you just charge it to that.' That's not the intended purpose of a credit score," said Rukavina.

## Legal ills

Although patients are sold the credit cards at their doctor's office, medical providers are generally not subject to a lawsuit under the federal Truth in Lending Act (TILA), which requires certain disclosures and is a defense to a debt owed.

"Once the medical care is charged on the credit card and the doctor is paid, the patient has no more responsibility to pay the doctor and the money is now owed to the

credit card," said Wilner.

However, state regulation of "loan brokers" may apply, said Chi Chi Wu, a staff attorney with the National Consumer Law Center in Boston.

"When a hospital, dentist or doctor pitches a credit card, there's a good argument that they are acting as a broker or loan arranger under state Credit Services Organization Acts," she said.

Claims against a medical provider for im-

proper disclosures could also fall under state unfair and deceptive practices laws, said Wilner.

Another issue is that many medical debt cases can eventually lead to a dispute over the quality of services or whether the medical services were completed.

Chase Health declined to comment for this article. GE CareCredit did not return calls. **MMLR**

*Questions or comments should be directed to the*

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### Stem Cell Disorders

- Aplastic Anemia (Severe)
- Fanconi Anemia
- Paroxysmal Nocturnal Hemoglobinuria (PNH)

### Acute Leukemias

- Acute Lymphoblastic Leukemia (ALL)
- Acute Myelogenous Leukemia (AML)
- Acute Biphenotypic Leukemia
- Acute Undifferentiated Leukemia

### Chronic Leukemias

- Chronic Myelogenous Leukemia (CML)
- Chronic Lymphocytic Leukemia (CLL)
- Juvenile Chronic Myelogenous Leukemia (JCML)
- Juvenile Myelomonocytic Leukemia (JMML)

### Myeloproliferative Disorders

- Acute Myelofibrosis
- Agnogenic Myeloid Metaplasia (myelofibrosis)
- Polycythemia Vera
- Essential Thrombocythemia

### Myelodysplastic Syndromes

- Refractory Anemia (RA)
- Refractory Anemia with Ringed Sideroblasts (RAS)
- Refractory Anemia with Excess Blasts (RAEB)
- Refractory Anemia with Excess Blasts in Transformation (RAEB-T)
- Chronic Myelomonocytic Leukemia (CMML)

### Lymphoproliferative Disorders

- Non-Hodgkin's Lymphoma
- Hodgkin's Disease
- Prolymphocytic Leukemia

### Liposomal Storage Diseases

- Mucopolysaccharidoses (MPS)
- Hunter Syndrome (MPS-IH)
- Scheie Syndrome (MPS-IS)
- Hunter's Syndrome (MPS-II)
- Sandhoff Syndrome (MPS-III)
- Morquio Syndrome (MPS-IV)
- Marfan-Lamy Syndrome (MPS-VI)
- Sly Syndrome, Beta-Glucuronidase Deficiency (MPS-VII)
- Adrenoleukodystrophy
- Mucopolidosis II (Hurler Disease)
- Krabbe Disease
- Gaucher's Disease
- Niemann-Pick Disease
- Wolman Disease

### Histiocytic Disorders

- Familial Erythrophagocytic Lymphohistiocytosis
- Histiocytosis-X
- Hemophagocytosis

### Phagocyte Disorders

- Chediak-Higashi Syndrome
- Chronic Granulomatous Disease
- Neutrophil Adkin Deficiency
- Retouler Dysgenesis

### Congenital Immune System Disorders

- Ataxia-Telangiectasia
- Kostmann Syndrome
- Leukocyte Adhesion Deficiency
- DiGeorge Syndrome
- Bare Lymphocyte Syndrome
- Omenn's Syndrome
- Severe Combined Immunodeficiency (SCID)
- SCID with Adenosine Deaminase Deficiency
- Absence of T & B Cells SCID
- Absence of T Cells, Normal B Cell SCID
- Common Variable Immunodeficiency
- Wiskott-Aldrich Syndrome
- X-Linked Lymphoproliferative Disorder

### Inherited Platelet Abnormalities

- Anegakaryocytosis / Congenital Thrombocytopenia

### Plasma Cell Disorders

- Multiple Myeloma
- Plasma Cell Leukemia
- Waldenstrom's Macroglobulinemia

### Inherited Erythrocyte Abnormalities

- Beta Thalassemia Major
- Pure Red Cell Aplasia
- Sickle Cell Disease

### Other Inherited Disorders

- Lesch-Nyhan Syndrome
- Curly-Hair Hypoplasia
- Glanzmann Thrombasthenia
- Okeleptosis

### Other Malignancies

- Breast Cancer
- Ewing Sarcoma
- Neuroblastoma
- Renal Cell Carcinoma

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