

## Rx FOR EXCELLENCE SEPT. 24: DETAILS ON HONOREES AND TICKETS INSIDE



### HIPAA regulations create new burden for providers

By Sylvia Hsieh

Health care entities can expect to keep busy in the coming year reviewing and revising their privacy notices and updating their contracts with related businesses in light of new proposed HIPAA rules.

The rules spell out the HIPAA obligations that Congress included in the HITECH (Health Information Technology for Economic and Clinical Health) Act, which passed in February 2009.

Most of the rules were expected, explaining how covered entities must update their privacy notices and detailing how penalties will be assessed for privacy breaches.

One surprise in the rules was the scope of the business associate rule, which is more expansive than expected.

That rule makes clear that the requirements under HIPAA – the Health Insurance Portability and Accountability Act – that already apply to business associates of health care providers, such as medical data contractors, auditors and law firms that represent providers, now also apply to subcontractors of those business associates.

“The requirements that previously ap-

plied to covered entities, such as health care providers, under HIPAA now apply in full force to business associates and subcontractors,” said David Harlow, an attorney in Newton, Mass., and principal of The Harlow Group, who blogs about health care law.

Business associates and their subcontractors must not only comply with privacy and data breach rules but, like covered entities, are now exposed to the full panoply of HIPAA penalties, which can reach as high as \$1.5 million per year.

“It covers a whole lot of different businesses that didn’t previously think they were covered. It could expand [HIPAA] exponentially,” said Amy Fehn, an attorney at Wachler & Associates in Royal Oak, Mich., who represents health care providers.

#### New notices ‘burdensome’

Covered entities will have to update notices of their privacy practices to reflect changes in the rules.

For example, the rules clarify that the sale of health information, such as for use by marketers, is prohibited without a patient’s authorization. There are also

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### First suit filed over injury during robotic surgery

By Nora Lockwood Toohar

A lawsuit filed in New Hampshire may trigger a rush of claims against hospitals for allowing surgeons to use a new surgical robot without proper training.

Sherry Long, 42, of Rochester, N.H., filed the suit in state court in May. Her ureters were accidentally cut during a hysterectomy using the daVinci surgical robot at Wentworth-Douglass Hospital in Dover,

N.H. last year.

The suit names the hospital and two doctors, and blames the injury on the operating surgeon’s lack of training on the use of the robot.

Long’s attorney, David Angueira, who practices at Swartz & Swartz in Boston, said that as far as he knows, the suit is the first in the nation claiming that improperly trained surgeons caused a patient injury using the

*Continued on page 16*

### Imaging disclosure causing concern

By Christina Pazzanese

Physicians are contending with a new law that requires non-radiologists who have imaging equipment in their offices to tell patients that they can choose to seek CT, MRI and PET imaging services at other facilities instead.

The provision, which is included in the Patient Protection and Affordable Care Act, also requires doctors to provide patients with a list of places that provide these services near their hometowns.

The change is intended to offer

patients greater transparency in doctor self-referrals and to curb the widespread use of imaging technology when it’s not essential for care.

Failure to comply with the law will result in a denial of reimbursements from the Centers for Medicare and Medicaid Services (CMS).

Attorneys who represent physicians say that the provision – which went into effect on Jan. 1 – is confusing and vaguely worded, and puts an unfair administrative onus on busy doctors.

“I think it’s a needless burden when you consider it in the context of all the things doctors have to do,” said attorney Dean P. Nicastro, who practices at Pierce & Mandell in Boston and formerly served as general counsel at the Massachusetts Medical Society. “This is just more paperwork.”

The good news is, however, that some relief from the new law’s requirements may be coming soon.

In the CY2011 Physicians Fee Schedule update that came out in

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# The impact of that one extra phone call

I will never forget the phone calls my dad – a general surgeon in Baltimore – made to his patients every night when I was a child.

He would call patient after patient to ask how each one was feeling after whatever procedure he or she had undergone earlier in the day. It didn't matter if he was tired, or if

the patient had to wake up for a moment to speak to him. What mattered – and still does today – is that he spoke to each of them.

The basic value of calling patients to check in soon after surgery was clear to me, but I never actually asked my dad about his motivation or the true difference these calls can make until two weeks ago.

"It's part of my continuity of care," he said. "Calling after surgery engenders better patient relationships."

He continued: "The increase in out-patient surgery means that patients are out the door two or three hours later. That's better for them physically, but it means the doctor-patient relationship as we know it is gone. We have to work harder to keep it up."

It's during that one extra phone call, he said, that a physician can remind patients of treatment details they missed in the recovery room or determine if a patient has a complication.

He gave an example: "I had an 82-year-old

patient and put in a catheter before discharge. When I called that night and asked him some questions, I could tell he was [ex-

periencing] urinary retention after a hernia repair."

He said some of his colleagues are surprised at the consistency of his

calling, choosing only to contact their "difficult cases."

"But how do you know they are difficult, until you call?" he wondered.

As my dad was speaking, I kept going back to the same conclusion: better communication = better patient care = better risk management.

The medical profession as a whole is strapped – strapped for time and strapped for resources. And yet these incremental investments of time spent communicating with patients can make all the difference, one phone call and one patient at a time.

Just ask my dad.

– Reni Gertner, MPH

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# Divided FDA panel urges more Avandia warnings

By Kimberly Atkins

In a fractured vote, a significant number of members of an advisory committee for the Food and Drug Administration voted in favor of removing the controversial diabetes drug Avandia from the market in light of a reported increased risk of heart attack and other health problems.

The majority of the panel, however, voted to keep the drug on the market, albeit with stronger warnings on its labeling and possible restrictions to its sale.

After two days of testimony from experts, 12 members of the 33-member FDA advisory group voted in favor of withdrawing the drug from the market, while 10 voted in favor of restricting the sale of the drug and requiring labeling changes to warn of possible serious risks. Seven members voted only for labeling changes, while three recommended no change at all.

A final decision on Avandia will be made by the FDA in the future.

Safety concerns and studies showing a link between the drug and an increased risk of heart attack prompted the FDA to issue a safety advisory for Avandia in April of 2009.

Thousands of Avandia users who have suffered heart attacks and other serious injuries have filed suit against drug maker GlaxoSmithKline in state and federal courts.

The lawsuits accuse the company of aggressively marketing Avandia and failing to warn patients about the increased risk of heart attacks, heart failure and strokes.

The same day as the panel vote, Bloomberg News reported that GlaxoSmithKline agreed to settle the majority of the lawsuits, awarding each plaintiff an average of about \$46,000 apiece. The deal apparently covers about 10,000 of the roughly 13,000 suits filed over the drug, according to the report.

Earlier news reports in June that thousands of Avandia cases had settled turned out to be incorrect, according to plaintiffs' lawyers and the drug company.

Sen. Tom Harkin, D-Iowa, who chairs the Senate Committee on Health, Education, Labor and Pensions, urged the FDA to consider the panel's recommendation and other expert testimony and studies carefully when making its final decision on the drug's fate.

"Avandia is a widely used drug, and it is imperative that the risks associated with its use be properly understood and vetted," said Harkin in a statement. "I urge FDA to carefully consider today's deliberations by the Joint Advisory Committee, and to make a final decision on how best to protect consumers as soon as possible. The safety of those suffering with diabetes must be our primary concern."

Meanwhile, a group of physicians has sued the FDA seeking to compel the agency to alert patients to safe dietary alternatives to Avandia and other diabetes drugs that

may pose a risk of heart attack, stroke and other complications.

The suit, filed in the U.S. District Court for the District of Columbia, accuses FDA commissioner Margaret Hamburg of failing to act on an administrative petition by the Physicians Committee for Responsible Medicine.

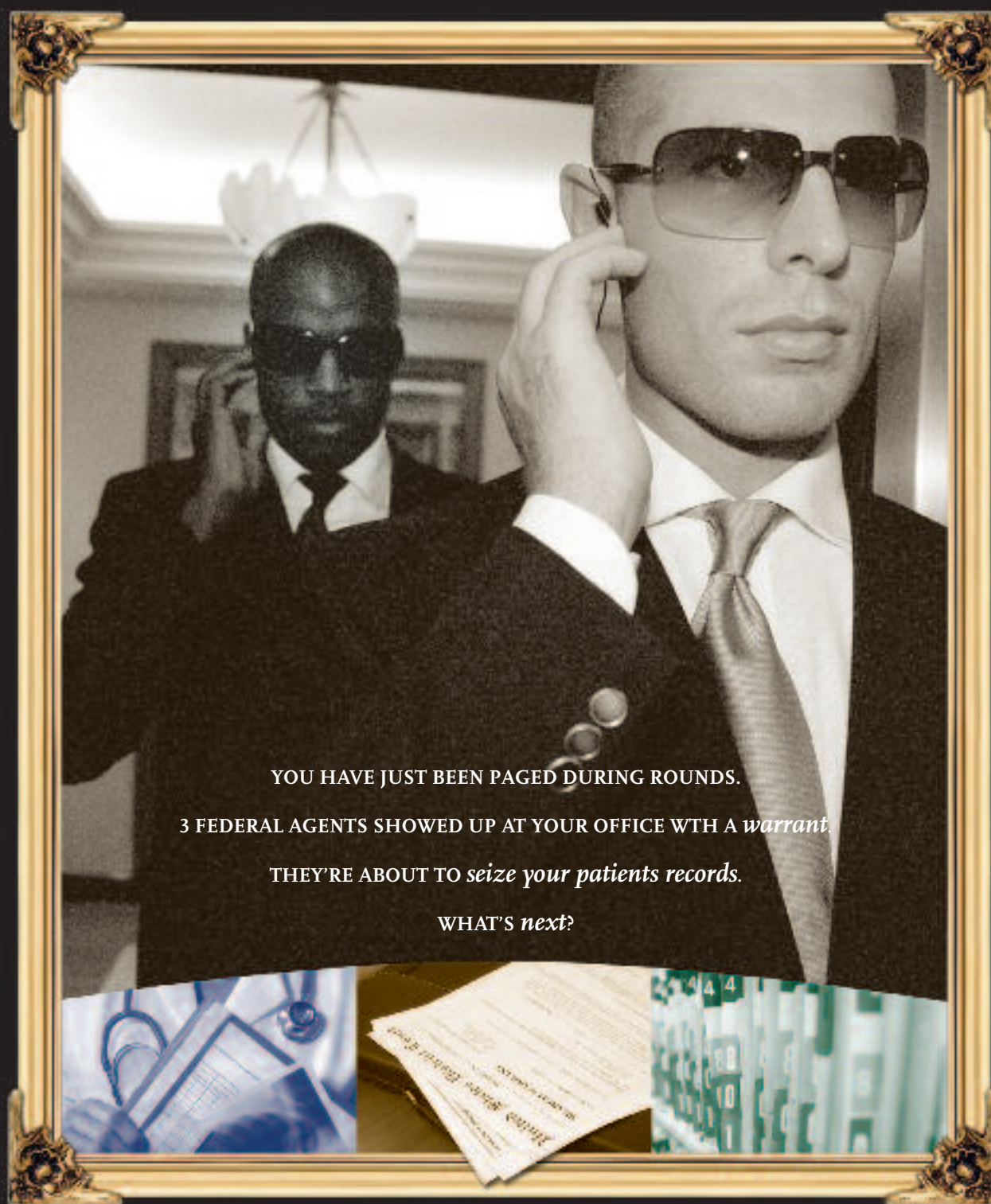
That petition urged the agency to require diabetes drugs to carry warning labels telling patients that low-fat plant-based diets can effectively treat type-2 diabetes without the dangerous side effects associated with oral medications.

"A plant-based diet is as effective as drugs for lowering blood sugar, and much more effective for trimming body weight," says PCRM president Neal Barnard, M.D. "Doctors and patients need the facts." **MMLR**

Questions or comments should be directed to the writer at: [kimberly.atkins@lawyersusaonline.com](mailto:kimberly.atkins@lawyersusaonline.com)



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# Listening In

The news beat of the medical profession

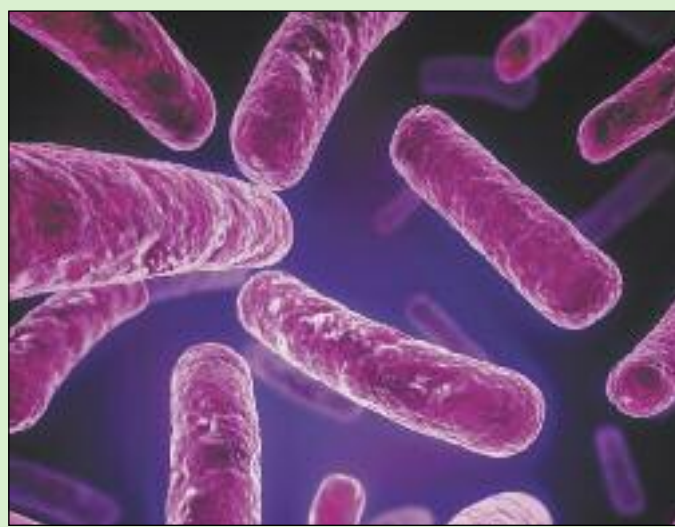
## Preventable infections weigh on hospitals

Hospitals are still struggling to prevent avoidable health care-associated infections, according to a survey of over 2,000 infection preventionists released by the Association for Professionals in Infection Control and Epidemiology.

Half of those surveyed agree that catheter-related bloodstream infections continue to be a problem in their facilities and cite lack of time, resources and the commitment of hospital leadership as hindering their ability to combat these infections more aggressively.

An estimated 80,000 patients a year in the U.S. develop catheter-related infections, and about 30,000 die from them, accounting for roughly one-third of the 99,000 deaths that occur each year from hospital-associated infections.

The average cost of care for a patient with this type of infection can exceed \$30,000, cost-



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ing the U.S. health care system more than \$2 billion annually.

Roughly 50 percent of respondents strongly agreed that their hospital administration knows the extent to which catheter-related infections are a problem, but only 30 percent strongly feel their administration is willing to spend the

money necessary to prevent them.

One in four respondents strongly believe that their facility monitors compliance with best practices for the prevention of bloodstream infections or holds clinical staff accountable for adhering to these practices.

## Nurses claim victory in pension ruling

An arbitrator has reinstated defined-benefit pensions for 250 union nurses at Cooley Dickinson Hospital.

Cooley Dickinson froze contributions to the defined-benefit pensions of 250 union registered nurses in January, according to Patri-

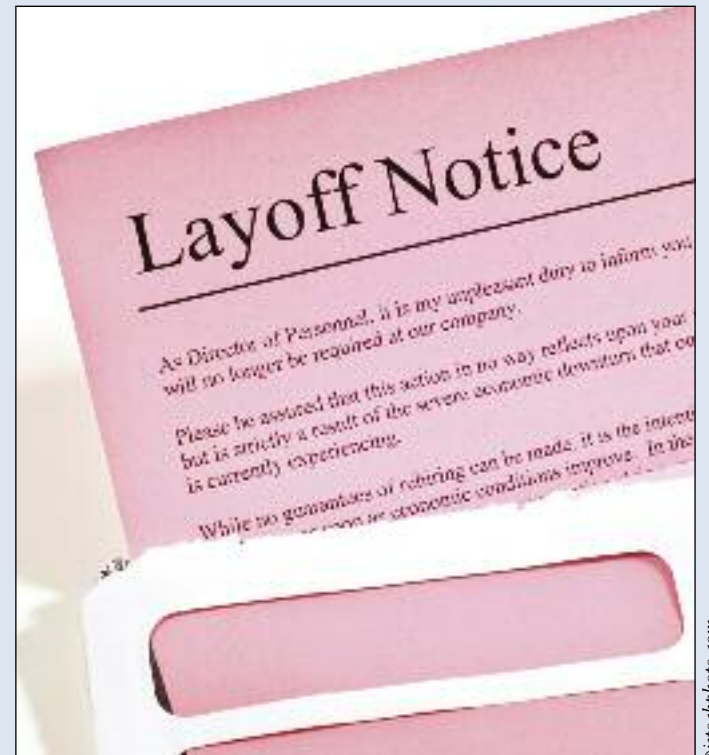
cia A. Williams, associate director of the Massachusetts Nurses Association labor union. The hospital offered to match worker contributions to a defined-contribution plan, like a 401(k) or 403(b).

But the changes were to have taken place in the middle of the nursing union's contract with the hospital, Williams said. The current three-year deal runs until Jan. 21, 2011.

The union filed a grievance and took the matter to arbitration, Williams said. An arbitrator ruled in favor of the union.

Cooley Dickinson had been putting pension contributions in an escrow account pending outcome of the arbitration, Williams said. The money will go to the pension fund, and payments will resume for at least the life of the current contract.

## Hospitals continue to cut jobs



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The Bureau of Labor Statistics reported that hospitals eliminated more jobs than they created in back-to-back months this summer, the first such occurrence in nearly 10 years, according to Health-Leaders Media.

Hospitals reported 2,200 payroll reductions in June, following 2,400 reductions in May. The last reported consecutive-month payroll reduction in was in 2000, when 2,200 jobs were lost between January and April.

Job growth in the health care sector continues to be powered by ambulatory services, which accounted for

7,400 payroll additions in June, and 62,900 payroll additions in the first half of 2010.

Nursing and residential care facilities reported 4,100 payroll additions, while physicians' offices reported 900 payroll reductions.

The health care sector has been one of the few areas of job growth during the recession and start of recovery, creating 96,000 new jobs in the first half of 2010, including 11,300 jobs at hospitals.

Over the past year, health care employment has grown by an average of 20,000 jobs per month, BLS figures show.

## Insurance caps remain; some hikes approved

Massachusetts Insurance Commissioner Joseph Murphy rejected three of seven proposed health care rate hikes proposed by Massachusetts insurers for policies that began July 1.

The other four insurance companies won single-digit rate increases for 63 plans sold in the so-called small-group market, which covers individuals and small businesses. Murphy said that those insurers showed

“more restraint” in their rate hike requests.

Overall, state regulators instituted a cap on prices for 137 health insurance plans up for renewal this summer, freezing rates at last year's levels.

Previously, regulators had denied 235 of 272 rate hikes proposed for the period from April to June. Insurers worked throughout the spring to challenge the rejection.

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## Internal medicine board sanctions docs in scandal

The American Board of Internal Medicine has sanctioned 139 physicians accused of collecting and sharing questions from its certification exam.

Modern Physician reported that the doctors allegedly disseminated the information through the Arora Board Review, a Livingston, N.J.-based test preparation service. The affected physicians had their certifications suspended or revoked.

A settlement was reached in June between the Board and two of the doctors named in the initial lawsuit. Related suits filed against five physicians in U.S. District Court in Philadelphia are pending.

Christine Cassel, M.D., Board president and CEO, said that letters were sent to all 139 doctors informing them that their certification was either revoked or suspended from one to five years “depending on the severity of our evidence of their unethical behavior.”

Although testing and validating exam questions is a two-year process, Cassel said that new exam questions are being developed and that there should not be delays for doctors seeking internal medicine certification.

## iPhone app for med students released

Medical publisher Elsevier and video game developer Legacy Interactive have released an application for Apple’s iPhone that features medical content and quizzes designed to allow medical students, residents and junior faculty to practice and improve their visual diagnosis skills.

Top Doc combines in-depth content with quizzes composed of more than 600 questions and answers developed for levels ranging from novice to expert. Users play against a timer as they try to determine the correct diagnosis by viewing actual photographs depicting a condition or abnormality.

Players’ performances are evaluated and given a grade, which they can automatically post to their Facebook account. Top Doc also provides the information in a non-competitive flashcard format.

Top Doc is available at Apple’s iTunes App store and retails for \$14.99.



## Study: Many docs don't report unfit colleagues

A new survey has found that many American physicians fail to report troubled colleagues to authorities, believing that someone else will take care of it, that nothing will happen if they act or that they could be targeted for retribution.

A surprising 17 percent of the doctors surveyed had direct, personal knowledge of an impaired or incompetent physician in their workplace, according to the study’s lead author, Catherine DesRoches of Harvard Medical School.

One-third of those doctors had not reported the matter to state authorities, hospital officials or state medical boards. The findings, which appeared in the Journal of the American Medical Association, are based on a 2009 survey of 1,891 physicians practicing in the U.S.

While there are programs for retraining doctors with weak skills and treatment available for medical professionals with addictions, the survey results suggest that doctors are not confident in the system, DesRoches said.

The American Medical Association and other professional groups say that doctors have an ethical



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obligation to make such reports. Many states require doctors to tell authorities about colleagues who endanger patients because of alcoholism, drug abuse or mental illness.

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# Bills, Rules & Regs



## From Beacon Hill

### House votes to repeal gift reporting law

Reversing course on a 2008 law aimed at diminishing pharmaceutical and medical device makers' influence on physicians, the House has voted to strike the so-called "gift ban" law, which critics say has hurt commerce in the medical and restaurant industries.

Opponents of the ban said it has discouraged out-of-state interests from doing business in Massachusetts and that it has not led to demonstrable reductions in health care costs. Supporters of the ban argue that the state has already heavily invested itself in implementing it. They also said that other states were pursuing similar bans and predicted that the law could help reduce health care costs and ensure that the interests of patients are physicians' top priority.

The elimination of the gift ban was included in economic development legislation that cleared the House 145-4. The Senate has approved a version of the bill that did not include the repeal.

### Health care payment overhaul postponed

Massachusetts' unprecedented plan to transform how hospitals and doctors are paid has been put on hold until 2011, largely because of disagreements among key officials, legislators and providers over how best to control health care spending, the Boston Globe reported.

A state commission recommended in 2009 that Massachusetts quickly adopt a new cost-conscious payment system. But while some want the legislation to guarantee patients' freedom to choose doctors and hospitals, others believe that limits are necessary for the plan to work.

Senate leaders and the Patrick administration disagree about how much authority a board that would oversee the new system should have over the actual fees paid to providers, while input from hospitals on the plan has varied widely.

Senate President Therese Murray noted that Senate leaders, administration officials and many providers agree broadly that the current payment system must change. She

said that she hopes all parties will be able to reach a consensus such that she can file legislation in 2011.

### Docs more engaged since health reform

A survey designed to track the progress of the doctor-patient relationship since the state's implementation of health care reform four years ago has revealed that physicians seem to be trying more than ever to learn important information about their patients, according to HealthLeaders Media.

The survey conducted by Massachusetts Health Quality Partners polled 56,000 adult patients and 22,000 parents of pediatric patients about their experiences with primary care physicians. Some 500 adult and pediatric primary care practices statewide participated.

In one of the response categories, "Knowledge of Patient," 70 percent of physicians said that they "always knew important information" about patients in 2009, compared to 67 percent in 2007. The study also revealed that 83 percent of patients said that their physicians were easy to understand and 82 percent said that their physician listened carefully.

There were also some negative aspects of the study's findings.

For example, 40 percent of adult patients and 35 percent of parents of pediatric patients reported that their physician did not always seem well-informed about the care they received from specialists. Also, about 30 percent of patients did not always receive follow-up reports on test results from the doctor's office visit, a statistic that has not changed since a 2007 study.

### Harvard Pilgrim agrees to lower rate increase

Harvard Pilgrim Health Care has struck a deal with state regulators to voluntarily limit its insurance rate increases for individuals and small businesses, a move the Patrick administration held up as evidence that its bold campaign to hold down health costs is working.

The Boston Globe reported that Harvard Pilgrim agreed to a rate increase for small firms and individuals in a range of 7 to 11 percent. Initially, it had requested increases averaging 8 to 12 percent for those policyholders.

The surprise agreement came just a week after an insurance appeals panel overturned a cap on Harvard Pilgrim's rates imposed by the state Division of Insurance. The state agency deemed the increases proposed by Harvard Pilgrim and other insurers to be excessive.

Other insurance carriers continue to appeal rate caps on their policy premiums.



## From Capitol Hill

### Congress OKs deferral of Medicare fee cuts

The House has passed a Senate-approved bill implementing a six-month deferral of the automatic 21-percent cuts in the Medicare physician fee schedule retroactive to June 1.

The measure, which passed by a vote of 417-1, also includes clarifications of the three-day payment window for hospital services, a data match program to identify providers that commit fraud and certain pension funding relief provisions.

The American Medical Association called the patch "a very temporary reprieve, ... not a solution," the Physician Law blog reported.

"In December, the Medicare physician payment cut will be a whopping 23 percent, increasing to nearly 30 percent in January. Congress is playing a dangerous game of Russian roulette with seniors' health care. Sick patients can't wait. Congress must replace the broken payment system before the damage is done and cannot be reversed," noted AMA president Cecil Wilson.

It appears likely that claims for services rendered after June 1 that were processed by Medicare carriers at the lower rate will need to be resubmitted. Further clarification from the Centers for Medicare and Medicaid Services is anticipated.

### House OKs restrictions on drug maker deals

The House has approved a measure restricting the ability of drug makers to enter into agreements that the Federal Trade Commission says keep generic medicines off the market, Bloomberg reported.

Under the measure, companies could be fined if the FTC and courts find that they are involved in settlements that preserve a brand-name pharmaceutical firm's patent by delaying a generic-drug maker's introduction of a lower-priced product. The proposal was included in a war-funding bill that was approved on a 239-182 vote.

The FTC contends that brand-name companies often offer generic drug manufacturers licensing rights on a product or other compensation in exchange for an agreement that delays the marketing of cheaper medications.

The legislation gives drug companies 30 days to appeal an FTC ruling on any deal.

### Obama skirts Congress with Berwick posting

President Barack Obama sidestepped Congress in a recess appointment, placing Harvard professor Dr. Donald Berwick in the top post at the Centers for Medicare and Medicaid Services.

Modern Physician reported that since Berwick's nomination in the spring, Republicans have been vocal in their criticism, due largely to his statements that seemingly favor the idea of holding back some medical treatments as a means to reduce soaring health care costs.

Berwick has been a long time friend of the provider community, many of who know him as the founder of the Institute of Healthcare Improvement in Cambridge. In June, the American Hospital Association, the Federation of American Hospitals and the Catholic Health Association all endorsed his nomination.

The Constitution allows for such procedural moves to be made, though most have come during longer breaks in the Congressional schedule.

CMS had been without a permanent director since 2006, when George W. Bush appointee Mark McClellan left the post. Berwick's appointment will hold until late 2011.

### FDA sued over failure to ban BPA

The Natural Resources Defense Council has filed a lawsuit against the Food and Drug Administration over its failure to act on a petition to ban bisphenol-A in food packaging and other materials.

The NRDC petitioned the FDA to ban the chemical – which is often found in baby bottles, sippy cups and other plastic products – in October 2008, but the agency has yet to respond.

During the 18 months since the petition was filed, the FDA has voiced its concerns about BPA, reversing its prior assertion that the chemical was safe. Also, the Environmental Protection Agency has listed BPA as a "chemical of concern."

"BPA-free alternatives are already available on the market. The FDA has no good reason to drag their feet banning it," Dr. Sarah Janssen, a senior scientist in the Environmental Public Health program at the NRDC, said in a statement.

Many states have already enacted laws banning BPA in products intended for young children.

The NRDC's petition seeks to ban BPA from all products and materials that involve food being exposed to the chemical. Studies have linked bisphenol A to neurological disruption, obesity, cancer and other serious health problems.

"The FDA has failed to safeguard the food supply and protect the public from harm," said Aaron Colangelo, an attorney at NRDC. "The FDA's failure to regulate this chemical in food packaging is unjustified, and so we are forced to ask the court to intervene and order the agency to take action."

The suit is pending in federal court in Washington, D.C.

– Allison McAndrew

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# Health care providers get incentive to go digital

By Sylvia Hsieh

Final regulations released by the Department of Human Services give hospitals and doctors' offices incentives to go digital.

Under the HITECH (Health Information Technology for Economic and Clinical Health) Act, providers can qualify for incentive payments if they make "meaningful use" of electronic health records. (See "Physicians must prepare for new EHR regulations," Massachusetts Medical Law Report, March 2010.)

The rule, which was announced on July 13 and clarifies the definition of "meaningful use," will be a pleasant surprise to health care providers who decried earlier proposals as too burdensome.

"The definition in the final rule is a lot more permissive than originally proposed. ... Across the board, the rule makes it easier to qualify for incentive funds," said David Harlow, an attorney and principal of The Harlow Group in Newton, Mass., who blogs about health care law.

For example, under an earlier version, providers would have had to meet 25 or 30 requirements to qualify for incentive payments, but the final rule instead requires that 15 requirements be met in the first year, said Harlow.

Then a provider can choose five requirements from the remaining 10 and defer compliance until the next year, he said.

The final rule also waters down an earlier requirement on electronic prescriptions from 75 percent to 40 percent.

Doctors' offices can receive as much as \$44,000 through Medicare and \$63,750 through Medicaid for installing computer systems that meet federal standards. Hospitals can receive millions of dollars.

HHS also recently released proposed rules spelling out HITECH's privacy and data breach requirements. (See page 1.) **MMLR**

Questions or comments should be directed to the writer at: [sylvia.hsich@lawyersusaonline.com](mailto:sylvia.hsich@lawyersusaonline.com)



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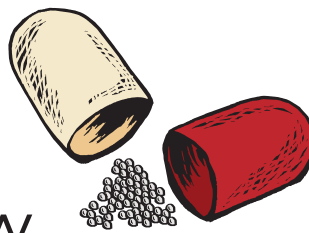


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# Good Medicine

What doctors are talking about now



**Q:** A recent bill in the Legislature would have given broad powers to a committee to oversee the practice of midwifery. To what extent should direct medical care be influenced by legislative or political efforts?

“Direct medical care should be provided based on the best medical evidence and recommendations of professional organizations. Prescription of specific care is beyond the expertise of our political and legislative bodies. Our current system of Certified Nurse Midwives working in collaboration with obstetricians works well to provide safe maternity care. CNMs are valued health care professionals, with high standards of education and training. The midwifery bill would have allowed the licensure of ‘lay midwives,’ many of whom have no formal education beyond high school and train through an apprentice program, and would be most likely to participate in home births with no supervision. Giving these individuals an official state licensure might be misleading to potential patients.”

— **Dr. Thomas Beatty, M.D., Chair of Obstetrics and Gynecology, Newton-Wellesley Hospital**



“Passage of this bill was intended to ensure that midwifery care is practiced safely throughout Massachusetts. The bill sought to improve access to midwifery services while ensuring the quality of care for a mother and her child before, during and after a birth. This bill illustrates the importance of continuing to guide medical care towards exceptional delivery and cost-effectiveness. To ensure the safety of patients across the Commonwealth, a certain measure of oversight is required so that consumers can be assured of healthy and safe treatment. We have remained at the forefront of health reform efforts in the country, and it is largely because of our commitment to the highest standards of quality.”

— **Sen. Richard T. Moore, chairman of the Joint Committee on Health Care Financing and lead sponsor of the midwifery bill**



“I don’t think the proposed bill was an example of medical care being influenced by legislation or political effort. The thrust of the bill was the creation of a body of peers that will regulate and oversee midwifery in the Commonwealth, just as the practices of nursing and medicine have regulation and oversight. Midwifery and all forms of medical care should be geared toward obtaining the best possible outcome for the patient. Consumers benefit when trades and professions are governed by minimum standards of competency and held accountable for deviations from those standards. Without this bill, midwifery will continue to stand alone as a medical profession without any professional oversight. The risks of substandard care are substantial, and legislation to try to reduce those risks makes sense.”

— **David P. McCormack, plaintiffs’ attorney at Sugarman & Sugarman, Boston, focuses on medical malpractice cases**



“Regulation of midwifery care in the homebirth setting is important so women can have increased access to quality maternity care. Midwifery care is associated with improved maternity outcomes in all settings, and homebirth care has been shown to be a safe option for low-risk women. Regulation of midwifery gives midwives protection from persecution and provides protection for consumers. Licensure would also pave the way for more insurance reimbursement, including Medicaid, so midwives can serve more low-income women. Providing licensure to homebirth midwives will increase access to midwifery care, along with reducing costs to states and improving maternity outcomes.”

— **Audra Karp, Certified Professional Midwife and co-president of the Massachusetts Midwives Alliance**



## Midwives legislation falls short on patient safety

By **Erin Tracy, M.D., M.P.H.**

Massachusetts has an enviable record of quality health care and patient safety. Yet state legislators took a giant step backward with House 4810, a bill that would have established a Board of Midwifery.

This bill – which would have licensed “lay midwives” (now called “certified professional midwives” after meeting some cursory requirements outlined by the Midwives Alliance of North America) with minimal educational and professional credentials – raised serious questions in three critical areas: the medical safety of pregnant women and their babies, the independent oversight of medical practice and the creation of clinical

standards of care in a legislative and political arena.

The character of this bill emerged early in its text. House 4810 defined midwifery as “the practice of providing the necessary supervision, care and advice to a client during normal pregnancy, labor, and the postpartum periods,” including, among other services, the “identification of physical, social, and emotional needs of the client.”

That seems straightforward enough, but then, in the very next paragraph, was this stunning declaration: “The practice of midwifery shall not constitute the practice of medicine, certified nurse-midwifery or emergency medical care to the extent that a midwife advises, attends or assists a woman during pregnancy, labor, natural childbirth or the postpartum period.”

Shall not constitute the practice of medicine? Declaring midwifery outside the practice of medicine was the bill’s most glaring shortcoming – and should by itself have provided ample reason for this bill to fail. But that was just the beginning.

House 4810 would have created an eight-member committee on midwifery (six of whom would have been midwives) with enormous, almost unlimited power.

According to the bill, this committee “shall make and publish such rules and regulations as it may deem necessary for the proper conduct of its duties.”

“Such rules and regulations,” the text continued, “shall be deemed approved unless disapproved within 15 days of submission to the public health commissioner provided, however, that any such disapproval shall be in writing setting forth the reasons for such disapproval.”

### Doctor’s Rx

This, in essence, is approval by default, not by active review and attention to standards of care.

Among other things, the bill also would have allowed this committee to establish all licensing, education and practice requirements for midwives, including “adoption of ethical standards and participation in peer review.”

Thus, House 4810 provided little, if any, independent oversight or regulation of midwives, except for what they may have determined for themselves. The care of pregnant women and their babies should hold as much importance as retail clinics – whose introduction in the Commonwealth resulted in the creation of expansive, precise regulations governing the delivery of care with input from medical professionals.

Further, the midwifery bill, besides allowing for the licensure and practice of lay midwives with minimal education and training, expanded their prescribing privileges beyond the well-established collaborative practices in the areas of obstetrics, gynecology and pediatrics.

State licensure, in the mind of the public, carries with it a stamp of legitimacy – that individuals who have such a license have met rigorous requirements and are adequately trained to provide safe, quality care. This was not the case with this legislation.

Then there was this, buried deep in the text of the bill: “The midwife shall only accept and provide care to those women who are expected to have a normal pregnancy, labor and delivery, as defined by the committee.”

The fact is that every pregnancy carries risk, and certain unpredictable obstetric and neonatal emergencies occur in low-risk individuals. If intervention is not offered within minutes, the outcome can be catastroph-

ic. Life threatening complications can occur rapidly and moderately frequently.

Proponents argued that the bill would contain costs, regulate a health care sector that is largely unregulated (certified professional midwives who do home deliveries), reduce Caesarean deliveries and address the shortage of OB-GYNs.

These are admirable goals, but no evidence exists that this bill would achieve any of them. And certainly, we should not trade the safety of mother and child for cost containment.

This bill fell far short in too many areas (a fact recognized by four medical societies, including the American Congress of Obstetricians and Gynecologists, which strongly opposed it) and offers an example of why the specific direction of medical care should remain beyond the purview of legislative and political influence.

Massachusetts has well-trained, competent nurse midwives and certified midwives who provide exceptional care to women. Experience has shown that where OB-GYNs and certified nurse-midwives and certified midwives collaborate in caring for women, the quality of those practices is enhanced by a working relationship characterized by mutual respect and trust, as well as responsibility and accountability. Expanding the numbers of midwives who are less trained is not necessary, and potentially dangerous, for women and their babies.

This measure failed in the just concluded legislative session, but it’s likely to return in the next session. In whatever form it resurfaces, it is imperative that proponents put patient safety, quality care, proper oversight and transparency above all else in a clear and convincing manner. The women of the Commonwealth and their babies deserve no less.

*Erin Tracy, M.D., M.P.H., an obstetrician-gynecologist, is Vice-Chair of the Massachusetts Section of the American Congress of Obstetricians and Gynecologists.*



# Imaging disclosure requirements causing concern

Continued from page 1

July, CMS proposed new guidelines to make compliance easier and more standardized for physicians.

## A complex requirement

Nicastro says that while he understands the rationale behind the new requirement, the process is not as simple as it sounds.

For one thing, the law itself does not specify how many suppliers should be on a given list, nor does it define the term "area" around a patient's residence when compiling such a list.

As a result, physicians have no way of knowing how much research they need to do to be in compliance, Nicastro said.

Regina Rockefeller, an attorney at Nixon Peabody in Boston, said that requiring doctors to provide a list of suppliers based on a patient's home address rather than the doctor's office location erroneously presumes that most patients seek medical care near their residence.

"I think when a lot of people need medical care, they're not at home," she said, noting that a patient could be on a business trip or on vacation. "Here in Boston, people are here for second opinions from all over the world."

It is far more reasonable, for example, to expect physicians on Cape Cod to be able to offer patients a list of local suppliers than it is to ask them to figure out who provides imaging services in other areas, she said.

"It is extremely hard to find out who the suppliers of CT scans are in Ann Arbor, Mich.," said Rockefeller.

Despite the law, Rockefeller said that most patients probably won't seek out another supplier, particularly in Massachusetts where the state already mandates residents

to have health insurance coverage.

"A patient with insurance has no motivation to shop around," she said.

Patients are likely to stick with their own doctor, believing that he or she will better understand and accommodate the urgency as well as the context in which the scans are being ordered.

"They have a relationship of trust with their physician and a preference for one-stop shopping," she said.

Lawrence W. Vernaglia, chair of the health care industry team at Foley & Lardner in Boston, says that the statute is further evidence that the government "remains hostile" to doctors who provide ancillary services in their offices and sees the provision as a way to "make patients distrustful of doctors."

But he contends that the talk of the statute's undue burden is overblown.

"It's not a big deal. It's just a piece of paper," said Vernaglia, who suggests that such lists can be assembled over a weekend by a Google-savvy office manager.

However, he agreed that some challenges remain. For example, the law requires that signed copies of the imaging suppliers' lists make their way into patients' files, and physician offices must have procedures in place to ensure this occurs.

Another critical aspect that is still unclear is whether physicians will be left open to liability claims for such referrals.

To be safe, Vernaglia suggests that doctors have their lawyers draft a disclaimer to add to the document before giving it to patients.

"A little exculpatory language wouldn't be a bad thing," he said.

## Relief on the way?

A proposed "clarification" of the rules, is-

sued by CMS in July, might make compliance easier for physicians.

Among the key proposed changes is that the list of service providers given to patients must include at least 10 suppliers and should be within a 25-mile radius of the physician's office, not the patient's home. If there aren't at least 10 suppliers in that location, then all suppliers in the 25-mile radius should be listed.

And although the Act stipulated that the disclosure requirements went into effect on Jan. 1, 2010, CMS proposes foregoing retroactive enforcement and putting the changes in effect as of Jan. 1, 2011 instead.

Vernaglia calls the CMS interpretations "very reasonable" and said if they are formally adopted, these clarifications should make it much easier for physicians to comply.

"They could have gone overboard and they chose not to," he said. "The fact that it's not retroactive is very good."

Though the current regulations include only CT, MRI and PET images, CMS appears to be considering whether to apply



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the requirements to other radiology and imaging services as well. **MMLR**

Questions or comments can be directed to the writer at: [christina.pazzanese@lawyersweekly.com](mailto:christina.pazzanese@lawyersweekly.com)

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# Verdicts & Settlements

## After Fosamax retrial, a tie score: Plaintiffs 1, Merck 1

By Sylvia Hsieh

The retrial of a Fosamax case that hung a jury last September has resulted in an \$8 million verdict for the plaintiff, a post-menopausal woman with previous periodontal disease who alleged that the osteoporosis drug caused her jaw bone to deteriorate.

This evens the score at 1-1 for the only two trials to reach verdict and providing no clarity for the remaining 1,500 cases. (In May, a jury came back with a defense verdict.)

The latest case involves facts typical of these cases and likely to be replayed in trials to come.

**“After treating this lady for eight years, [the doctor’s] only conclusion was that Fosamax did this, because the bone was not responding to other treatments.”**

— Timothy O’Brien

The first jury reportedly deadlocked at 7-1 in favor of Merck; the second jury took less than four hours to award \$8 million in damages, exceeding the \$5 million the plaintiff asked for.

Timothy O’Brien, the attorney who tried both cases, said that the main difference between the two trials was live testimony from the plaintiff’s oral surgeon that threw the defense off its strategy.

“At the first trial, the defense blamed the oral surgeon for causing [the jaw deterioration]. He came to trial this time and the defense wasn’t expecting it. They clearly thought we were going to try the case in the exact same way,” said O’Brien, a partner at Levin, Papantonio, Thomas, Mitchell, Echsner & Proctor in Pensacola, Fla.

But Merck’s attorney blamed the June verdict on one of the plaintiff’s attorneys’ mischaracterizations of defense expert testimony in closing arguments.

“We believe the jury verdict was the result of plaintiff’s counsel’s inflammatory and prejudicial remarks,” said Paul Strain of Venable in Baltimore, who defended the case.

### Tooth extraction

The plaintiff, Shirley Boles, was 59 when her doctor prescribed Fosamax to prevent osteoporosis. She took the drug for nine years beginning in 1997.

In 2002, after she had two teeth extracted, she developed an infection of the bone marrow in her jaw bone.

In the familiar battle over causation, Boles alleged that Fosamax caused a unique disease called osteonecrosis, or death of the

jaw bone, while Merck contended that poor dental hygiene caused the infection, pointing to the fact that she had lost 24 teeth by age 56.

But O’Brien said this fact worked in his client’s favor.

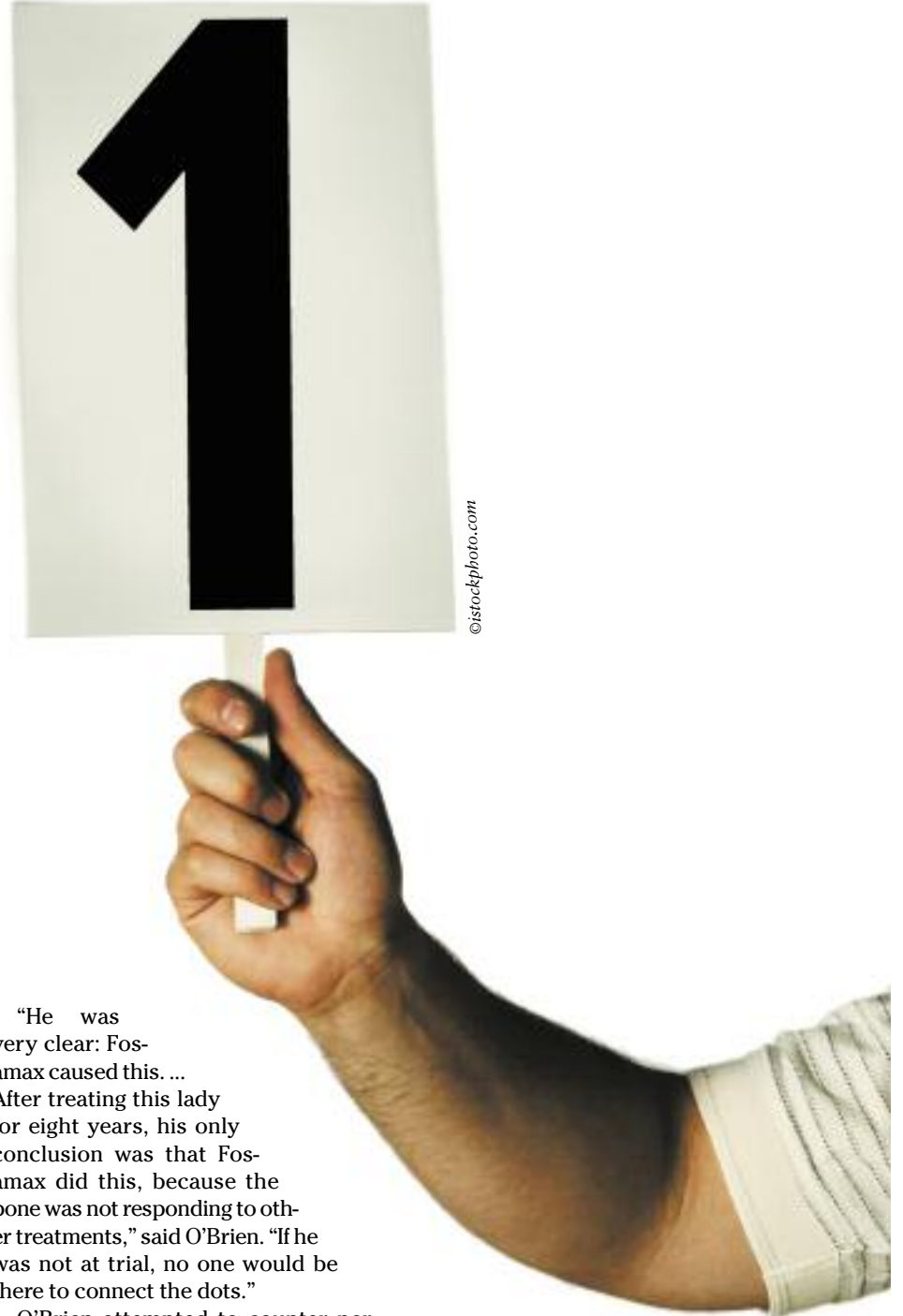
“With all the other teeth extracted before 1997, she never had a failure to heal. So the first time she had a tooth extracted after she was taking Fosamax, all hell broke loose,” O’Brien said.

Unlike the first trial, where Merck pointed the finger at an absent witness, Boles’ oral surgeon, for subpar surgery, this time O’Brien took away that argument by pro-

ducing the oral surgeon at trial.

“We deposed him, and he was on the witness list, but [the defense] seemed surprised. They just assumed he wasn’t going to take time out to come to New York from Shalimar, Fla.” because he didn’t for the first trial, said O’Brien, who flew the busy surgeon in on his firm’s private jet.

Aside from defending his surgery, the surgeon also testified that the reason he didn’t identify the plaintiff’s injury as bisphosphonate-induced osteonecrosis of the jaw early on was because the condition was not in the medical literature at the time, said O’Brien.



“He was very clear: Fosamax caused this. ... After treating this lady for eight years, his only conclusion was that Fosamax did this, because the bone was not responding to other treatments,” said O’Brien. “If he was not at trial, no one would be there to connect the dots.”

O’Brien attempted to counter perhaps the strongest defense argument – that Fosamax has benefited millions of women – by arguing that the drug only benefited a small group of women.

The now 72-year old Boles, a retired sheriff’s deputy known along with her female partner as the “Cagney and Lacey” of the Florida Panhandle, told an urban New York jury in federal court that she trusted her doctor and her doctor trusted Merck and that’s why she took Fosamax – to “do something good for herself.”

According to O’Brien, Merck’s own adverse events reports indicated that the drug only benefits women who already have low bone density or a prior vertebral fracture.

“My client was not in either of those groups,” O’Brien said.

### Judge blasts attorney

During closing arguments, one of the plaintiff’s attorneys, Gary Douglas of Douglas & London in New York, made two statements that did not cause another mistrial but did rile the judge.

First, he summarized defense testimony as concluding that there is no benefit from Fosamax for women who don’t have osteoporosis.

“This unfair quotation left off the concluding sentence that there is a benefit to the category of women who are pre-osteoporosis or considered to have osteopenia [low bone density],” said Strain.

Second, he urged the jury to “say something to Merck” – which is classic language for requesting punitive damages – even though punitive damages were already off the table.

“The judge had already found as a fact that the plaintiff could not make out a case for punitive damages,” Strain said.

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The trial judge read the full version of the relevant defense testimony to the jury, gave a curative jury instruction that they were not to “send a message” to anyone on damages, and blasted the plaintiff’s attorney, saying that he had “never heard a more outrageous summation in [his] life.”

In a post-trial hearing, the judge ordered Douglas to appear again to explain why he should not impose sanctions and refer him to the disciplinary committee.

He also issued a written order finding that Douglas “repeatedly disparage[d] defense witnesses and generally act[ed] rudely to defense counsel in a manner that cannot be fully captured in the record: using sarcasm, gestures, imitations, mockery, singing, derogatory tones, laughing, and admittedly ‘fooling around’ and ‘making fun.’”

Douglas did not return a call seeking comment for this article.

Yet, at the close of trial, the judge denied Merck’s motion for a mistrial on those grounds.

Strain, Merck’s attorney, said he will try again to seek a directed verdict or a new trial.

If Strain doesn’t get a third bite at the apple in the Boles case, the next Fosamax trial is slated for November, with no signs of any cases settling.

“Merck is committed to trying these cases,” said Strain, who made no offers to the plaintiff in the Boles case.

With over 1,500 claims waiting in the wings, both sides will have plenty of chances to try, try again. **MMLR**

Questions or comments can be directed to the writer at: [sylvia.hsieh@lawyersusaonline.com](mailto:sylvia.hsieh@lawyersusaonline.com)

# Verdicts & Settlements

## Man undergoes gastric bypass; fatal heart attack follows

A 55-year-old morbidly obese man was scheduled for a gastric bypass procedure.

Prior to the surgery, he underwent pre-operative testing, from which the doctor concluded that despite the patient's pre-existing hypertension, sleep apnea and chronic hypoxia, no contraindications to surgery existed.

The patient underwent the procedure in August 2002. There were no complications.

During the patient's post-operative course, his wife repeatedly reported her husband's deteriorating respiratory condition, yet his medical records did not document any decline. While the records documented that his lungs were clear, he also reportedly received nebulizer treatments.

The patient also received two units of packed red blood cells, but again, there was no indication in the medical chart as to the reason for the transfusions. In fact, not a single entry was made in his chart following post-operative day 1. The doctor claimed that he visited with the patient each day after the operation and that he was doing well.

The man woke in the hospital one morning and was noted to be "wheezy" and short of breath. There was no indication in the medical chart that any testing was performed to determine the potential cause of his declining respiratory status.

At approximately 8 p.m. that night, he requested to use the bathroom, where he suffered a sudden cardiac event. A code blue was called, but despite more than 45 minutes of resuscitation efforts, the patient died.

An autopsy revealed evidence of pulmonary congestion, which the patient's medical expert was prepared to testify was highly suggestive of congestive heart failure.

Medical experts were prepared to testi-



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fy that the doctor failed to properly manage the patient's post-operative care and allowed his condition to deteriorate for several days following his surgical procedure.

A cardiology expert was prepared to testify that the patient exhibited classic signs and symptoms of congestive heart failure that were not adequately evaluated and treated, and which ultimately led to his death. He was prepared to testify that had

appropriate treatment been initiated – even as late as the morning of his death – the patient's congestive heart failure would likely have been reversed and he would not have suffered the fatal cardiac event.

The doctor's expert witnesses were prepared to argue that the patient did not die as a result of congestive heart failure, but rather of a sudden cardiac event of unknown origin and that the autopsy report

supported their position.

The case settled shortly before trial for \$435,000.

**Type of action:** Medical malpractice

**Injuries alleged:** Wrongful death

**Date:** March 2010

**Submitted by:** Eric J. Parker and Susan M. Bourque, Parker Scheer, Boston

## Verdict & Settlement Reports

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 health care providers as well as plaintiffs, in addition to settlements.

**If you have an item you would like to submit, please contact Matt Yas at [matt.yas@lawyersweekly.com](mailto:matt.yas@lawyersweekly.com) or 617-218-8152.**

## Verdicts & Settlements

Continued from page 11

### Woman's death blamed on delayed treatment of colitis

A 59-year-old woman died of septic shock secondary to a delay in diagnosis and treatment of her ischemic colitis.

The patient presented to the ER in the afternoon with complaints of abdominal pain that had progressively worsened over a week, epigastric pain, left shoulder and breast pain, dizziness, nausea and diarrhea.

The ER doctor examined the patient and noted that her abdomen was soft with diffuse tenderness to palpation. She was medicated for pain with 4 mg of morphine.

As her stay in the ER extended into the evening, the patient continued to complain of worsening pain. She underwent an abdominal CT scan, which revealed diverticulosis as reported by the radiologist.

After more morphine and Tylenol, the patient's pain level improved and she was discharged with instructions to return to the ER in the event of worsening pain, fever or other concerns, and to follow up with her primary care physician the following day.

The next day, the patient returned to the ER with complaints of severe persistent abdominal pain across the lower right and left quadrant, radiating as a sharp, cramping pain up to the diaphragm. Laboratory studies revealed that she was suffering from septic shock.

She underwent a repeat abdominal/pelvic CT scan that revealed new development of several areas of free air seen within the peritoneal cavity when compared with the previous study.

She was immediately taken to the OR, where she was found to have gangrene of the small bowel and perforation of the cecum with free stool in the area.

She was transferred to the surgical ICU where she required aggressive fluid boluses and multiple pressors in order to maintain her blood pressure. She continued to be acidotic even after infusions of bicarbonate. Despite these interventions, she went into cardiac arrest and died.

The woman's attorneys contended that the radiologist who reviewed the initial CT scan failed to identify and report findings of impaired blood flow on the abdominal and pelvic scan and failed to recommend an urgent surgical consultation.

The radiologist contended that the CT did not show any evidence of impaired blood flow.

The case settled following discovery for \$1.5 million.

### Patient's breast cancer goes undiagnosed despite lump

The patient was 53 when she first saw her primary care physician. She had a lump in her left breast that had presented as "architectural distortion" on a mammogram taken several years earlier.

She had some pain at the time of her exam and was sent by her PCP for a mammogram and ultrasound. Both studies came back normal and unchanged from earlier evaluations.

One year later, she transferred her care to a new PCP. During her initial exam, she reported increased sensitivity but no evidence of a mass. A mammogram again came back normal. She did not return to the second PCP for two years.

At the appointment two years later, the patient reported that her nipple had inverted slightly and that her breast was bigger, fuller and tenser.

She was referred to a breast surgeon who diagnosed her with invasive carcinoma. She received six cycles of chemotherapy as well as a mastectomy.

Unfortunately, she died two years after her diagnosis, leaving a husband and two daughters.



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The doctors and their corporate employers argued that the referral to a breast specialist was not indicated in light of the normal radiographic findings. They argued that the patient's cancer had progressed too far by the time they had become involved for treatment to have changed the outcome. They also argued that the patient was non-compliant with her own follow-up care.

The case settled prior to trial for \$1 million.

**Type of action:** Medical malpractice  
**Injuries alleged:** Failure to diagnose breast cancer

**Date:** May 2010

**Submitted by:** Philip J. Crowe Jr. and Michael J. Harris, Crowe & Mulvey, Boston

**Type of action:** Medical malpractice

**Injuries alleged:** Death from bowel necrosis

**Date:** May 2010

**Submitted by:** Andrew C. Meyer and William J. Thompson, Lubin & Meyer, Boston

### Nurse takes surgeon to court following botched surgery

A 41-year-old registered nurse and mother of two suffered a back injury while moving a patient. Her initial injury was an annular tear with no herniations. The surgeon elected to perform a lumbar fusion.

The first post-operative report contradicted the operative report in stating that the graft became displaced when the patient was "flipped" from the supine to the prone position during surgery. The operative report stated that the grafts were well placed.

The doctor testified at his deposition that a displaced graft can pose a danger to the patient, including spinal instability and compression of the iliac veins. X-rays showed that the graft was approximately 50 percent displaced anteriorly in the area of the iliac arteries. Despite knowledge of the displacement, the physician failed to order further diagnostic imaging to investigate whether the displacement was causing a vascular compromise.

The nurse sought a second opinion. After examination of the X-rays showing the anterior displacement, a CT angiogram revealed displacement of the iliac arteries and that the graft was deforming the left iliac vein.

The patient subsequently underwent two emergency revision surgeries. She has been left with constant low back pain that interferes with her daily life. She has developed nerve damage from her back into her legs, as well as neuropathy at the surgical sites, constant pins and needles in her right thighs and legs and urinary dysfunction.

The surgeon and his employing corporation contended that the surgery performed was reasonable under the circumstances and that prior conservative treatment had not been successful.

The nurse's medical expert was expected to testify that the physician failed to seek and/or exhaust conservative treatments before performing surgery, that he failed to properly perform the grafts to ensure that they would not become displaced and that he should have become aware of the displacement and immediately repaired the graft.

The patient is partially and permanently disabled and presently unable to return to her job as a registered nurse. The case settled for \$1.5 million.

**Type of action:** Medical malpractice  
**Injuries alleged:** Vascular compromise requiring surgical revision, resulting in constant pain and loss of function

**Date:** April 2010

**Submitted by:** Neil Sugarman and David P. McCormack, Sugarman & Sugarman, Boston

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## Course Information

### Intended Audience

This course is intended for physicians and allied health professionals.

### Course Objectives

- Inform physicians and other health care providers about the key provisions of the new Massachusetts privacy standards, 201 CMR 17.00.
- Emphasize the components of a comprehensive Written Information Security Program (WISP).
- Discuss the potential consequences of failing to comply with the privacy standards.
- Review key questions about your practice to determine compliance.

### Course Credit

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## Bibliography – see page 15

# Physician practices scramble to comply with new privacy reg



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## By Eric T. Berkman

Physicians in many small practices are still struggling to comply with Massachusetts' sweeping new data privacy regulation that went into effect on March 1 – and many doctors aren't even aware of the changes.

The regulation, 201 CMR 17.0, requires any organization – including health care providers – with access to personal data of Massachusetts residents to maintain a rigorous program to proactively prevent identity theft.

Specifically, organizations must have a comprehensive written information security program (WISP), train all employees on the program, implement a wide array of information-security procedures and certify compliance of all outside service providers. (For more information on the major provisions of the reg, see "The details of the new privacy rules," on page 10.)

Full compliance was required by March 1, but legal experts say that very few providers – particularly those in small practices – are aware of the regulation at all, much less compliant with it.

Meanwhile, those actively seeking to comply are confronting tough technical, organizational and financial challenges in a time when medical practices are already grappling with federal regulatory schemes, including constantly changing Health Insurance Portability and Accountability Act

(HIPAA) rules, meaningful use of electronic health records and "red flag" rules mandating that providers detect and respond to security breaches.

Though nobody expects the state Attorney General's Office – which has yet to announce enforcement policies under the rules – to audit organizations for compliance in advance of a breach, noncompliance is not an option. The rule calls for penalties in the amount of \$100 per Massachusetts resident affected by a breach, up to a maximum penalty of \$50,000 per violation.

If your practice's data is breached, experts expect the attorney general to investigate whether you are in compliance. If your practice doesn't measure up, you risk heavy fines, lawsuits and state monitoring, not to mention horrific public relations fallout.

"If your database of patient information is hacked and there's an identity theft, people will think twice about going back to your practice," says William E. Hannum III, an attorney at Schwartz Hannum in Andover who has been advising businesses on complying with the new regs. "That's headline-grabbing stuff."

## Difficult to comply

Framingham lawyer Stephen E. Meltzer, who maintains a blog on data privacy and security and lectures frequently on the topic, estimates that 75 to 80 percent of

large organizations – including hospitals and large health care organizations – are in compliance. But smaller organizations, which lack the same resources, are not even close.

"About half the people I've spoken to saw delays in implementation and decided they'd just wait. The other half don't even know this exists," says Meltzer. "I'd say readiness for small business is probably around 10 to 15 percent ... And I'd say small physician practices are lumped in with the rest of small business in terms of readiness."

Those working to comply are finding the process difficult. One complexity is that many of the federal regs deal with data privacy, but may not necessarily mesh well with the Massachusetts reg.

Making matters worse, the new privacy rule provides no specific guidance for health care organizations.

"Trying to make sure it all adds up is very challenging and frustrating," says Anuj K. Goel, the Massachusetts Hospital Association's vice president of legal and regulatory affairs.

"People want to do the right thing, but with everything happening already, and the state now adding more and more requirements, this takes time and resources to figure it all out."

Eduard Goodman, chief privacy officer at Identity Theft 911, an Ari-

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# Physician practices scramble to comply with privacy reg

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zona-based company that's helping providers comply with the new Massachusetts rule, says the biggest challenge he's seeing is the intimidation factor.

"In my experience, with physicians there's an automatic apprehension about a new regulation and anything that affects their day-to-day," says Goodman, who is also an attorney. "Most doctors just want to be doctors, so the first hurdle is just recognizing that this is a requirement and digging in instead of putting it off."

Meltzer agrees, saying doctors need to do something to get started. He suggests having a couple of physicians in the group who understand the business start by identifying what data the practice has electronically and on paper.

"Once you get started, it'll start to make more and more sense," he says.

## Tips for compliance

Here are some tips to help physician practices comply with the new rules:

- *Make sure all electronic information is protected.*

Goodman says many physicians don't realize all the places where digital data is stored.

Protecting personal information that is stored electronically means more than securing your computers, network and servers.

Many photocopiers, for example, have built-in hard drives.

"If you didn't set it up right and you're leasing it, you'd better [make certain] that whoever you're leasing it from is taking care and scrubbing that data if you're not doing it yourself," Goodman says.

Similarly, most physicians don't realize that their printers have built-in hard drives or flash memory that might be storing sensitive information like Social Security numbers, credit card data and medical information.

"Very rarely do [providers] go

the extra yard and consider what they're doing to secure copiers, smartphones, flash drives and printers," says Goodman. "These devices aren't named in the regulation, but they're covered within [its] scope and are just not getting the attention they deserve from the security perspective."

- *Secure employee records.*

While medical practices generally have patient information locked down to comply with HIPAA, employee information often sits out in an unsecure manner and is often on paper, says Hannum.

He urges providers to secure that information and to minimize the amount that's retained in the first place.

"If you don't need it, don't keep it," he says. "And when you shred it, you can't just run it through a \$20 shredder from OfficeMax. The [regulation] uses terms like 'pulverize' – destroyed in a way where it can't be reconstituted."

- *Seek help from experts.*

Finally, says Hannum, engage both a lawyer and an IT consultant to help you get into compliance. Each has critical expertise that the other doesn't have.

Once you have your WISP in place, it's crucial to treat it as a living, breathing document, rather than just filing it and calling it a day.

"There needs to be ongoing maintenance," Hannum says. "This means continuous training of employees, monitoring policies, procedures and IT measures and certifying compliance when engaging with new vendors."

He also recommends making one employee the practice's "data security chief." It might be a good role for someone who already handles human resources, Hannum says.

**MMLR**

*Questions or comments should be directed to the editor at: [reni.gertner@mamedicalaw.com](mailto:reni.gertner@mamedicalaw.com)*

## The details of the new privacy rules

Here is a look at the major provisions of the new privacy regulation. These rules apply to all businesses that own or license personal information, including health care providers.

### The comprehensive written information security program (WISP)

The rule requires any business that owns or licenses personal information to "develop, implement and maintain a comprehensive information security program" to secure that information.

Any program must:

- Designate an employee to maintain the WISP.
- Identify and assess reasonably foreseeable risks (internal and external).
- Develop security policies for keeping, accessing and transporting records.
- Impose disciplinary measures for violations of the program.
- Prevent access by terminated employees.
- Oversee service providers and contractually ensure compliance.
- Restrict physical access to records.
- Monitor security practices to ensure effectiveness and make changes if warranted.
- Review the program at least annually.
- Document responsive actions to breaches.

The program must be "consistent with the safeguards for protection of personal information and information of a similar character set forth in any state or federal regulations by which the person who owns or licenses such information may be regulated." It also must "contain administrative, technical and physical safeguards that are appropriate to" the specific business, its resources, the amount of information it stores and the need for security of both consumer and employee information.

### Breach notification requirements

Under the new law, if the possessor or owner of personal information knows – or has reason to know – that a breach has occurred, it triggers the rule's notification requirement. This includes any breach of security or unauthorized use or acquisition of personal information. A possessor (who is not an owner) must notify the owner of

the breach. The owner must notify the Attorney General, the Office of Consumer Affairs and Business Regulation and the affected Massachusetts resident.

### Security procedures for electronic information

Businesses, including health care providers, covered by the new regulations that store personal information electronically must include technical security procedures in their written policies. Procedures must in place to protect computer systems, networks and portable devices, including wireless systems.

A computer security policy must include:

- Secure user authentication protocols, including unique user identification, strong passwords, access restricted to active user accounts and access blocked after multiple unsuccessful login attempts.
- Secure access control measures, restricting access to records that contain personal information to employees who need it to perform their job duties.
- Encryption of information transmitted over public or wireless networks.
- Monitoring of computer systems for unauthorized use or access to personal information.
- Encryption of all personal information stored on laptops or portable devices.
- Firewall systems and security patches for any computer system that contains personal information and is connected to the Internet.
- Security software, including antivirus and malware protection software with up-to-date patches and virus definitions.
- Education and training of employees on the proper use of the systems to secure personal information.

### Data destruction procedures

After documents no longer need to be retained, the law requires that paper records be subject to redaction, burning, pulverizing and/or shredding such that personal information cannot be read or reconstructed.

Electronic information must also be destroyed in such a fashion that personal information cannot be read or reconstructed. **MMLR**

– Reni Gertner

## The Physician's Corner

# The new standards for protecting Mass. residents' personal information

By Henry Tulgan, MD, FACP

Just as physician practices and other health care providers have been working to modify their operations to comply with new federal rules under the 2009 HITECH (Health Information Technology for Economic and Clinical Health) Act, another new set of rules establishes additional standards for the Commonwealth.

These standards apply to individuals or entities that own or license personal information regarding Massachusetts residents. They apply to both paper and electronic records and essentially protect consumers from any potential harm or inconvenience due to a data breach.

These rules most definitely apply to members of the health care industry, including the smallest of physician practices.

Like HITECH, the state standards cover security breaches. The state rules provide specific examples defining what personal information is protected.

The standards also require the development, implementation

and maintenance of security procedures that must be written and require protection of both patient and employee data.

Such a program includes, among other things, designating responsible individuals, assessing risks, training, compliance and discipline, as well as ensuring that third party contracted services are in compliance.

Annual review is mandatory, in addition to upgrading systems when necessary. These systems must also cover computers and other office equipment, passwords, encryption, restricted access and access issues by terminated employees – which may trigger major overhauls. Employee training must include introduction to security and familiarity with the organization's security systems.

Although the standards required these steps to be taken by March 1, many practices may not yet be in full compliance. And penalties may be severe: \$100 per resident whose information is breached, up to a maximum of \$50,000.

Advice from legal experts – and you may want to consult one – is to take steps to reach full compliance as soon as possible. That may also require outside identity theft expertise and skilled information technology personnel, especially in a small practice environment.

Meanwhile, many practices are designating individuals or departments, such as Human Resources, with functions that relate to these standards to assume responsibility for compliance.

Although the new standards are now specifically geared toward Massachusetts practitioners, it will not be long before other states follow suit, so the prudent course is to be prepared wherever you may be located. The checklist below, developed by the Massachusetts Office of Consumer Affairs and Business Regulation, may be a useful tool in implementing and refining the application of these standards into your practice.

### 201 CMR 17.00 Compliance Checklist

*Written Information Security*

#### Program (WISP)

- ✓ Do you have a comprehensive, written information security program ("WISP") applicable to all records containing personal information about a resident of the Commonwealth of Massachusetts?
- ✓ Does the WISP include administrative, technical, and physical safeguards for personal information protection?
- ✓ Have you designated one or more employees to maintain and supervise WISP implementation and performance?
- ✓ Have you identified the paper, electronic and other records, computing systems, and storage media, including laptops and portable devices, that contain personal information?
- ✓ Have you chosen, as an alternative, to treat all your records as if they all contained personal information?
- ✓ Have you identified and evaluated reasonably foreseeable internal and external risks to paper and electronic records containing personal information?
- ✓ Have you evaluated the effec-

tiveness of current safeguards?

- ✓ Does the WISP include regular ongoing employee training, and procedures for monitoring employee compliance?
- ✓ Does the WISP include disciplinary measures for violators?
- ✓ Does the WISP include policies and procedures for when and how records containing personal information should be kept, accessed or transported off your business premises?
- ✓ Does the WISP provide for immediately blocking terminated employees' physical and electronic access to personal information records (including deactivating their passwords and user names)?
- ✓ Have you taken reasonable steps to select and retain a third-party service provider that is capable of maintaining appropriate security measures consistent with 201 CMR 17.00?
- ✓ Have you required such third-party service provider by contract to implement and maintain such appropriate security measures?

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# The new standards for protecting Mass. residents' personal information

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- ✓ Is the amount of personal information that you have collected limited to the amount reasonably necessary to accomplish your legitimate business purposes, or to comply with state or federal regulations?
- ✓ Is the length of time that you are storing records containing personal information limited to the time reasonably necessary to accomplish your legitimate business purpose or to comply with state or federal regulations?
- ✓ Is access to personal information records limited to those persons who have a "need to know" in connection with your legitimate business purpose, or in order to comply with state or federal regulations?
- ✓ In your WISP, have you specified the manner in which physical access to personal information records is to be restricted?
- ✓ Have you stored your records and data containing personal information in locked facilities, storage areas or containers?
- ✓ Have you instituted a procedure for regularly monitoring to ensure that the WISP is operating in a manner reasonably calculated to prevent unauthorized access to or unauthorized use of personal information; and for upgrading it as necessary?
- ✓ Are your security measures reviewed at least annually, or whenever there is a material change in business practices that may affect the security or integrity of personal information records?

✓ Do you have in place a procedure for documenting any actions taken in connection with any breach of security; and does that procedure require post-incident review of events and actions taken to improve security?

**Additional Requirements for Electronic Records**

- ✓ Do you have in place secure authentication protocols that provide for:
  - Control of user IDs and other identifiers?
  - A reasonably secure method of assigning/selecting passwords, or for use of unique identifier technologies (such as biometrics or token devices)?
  - Control of data security passwords such that passwords are kept in a location and/or format that does not compromise the security of the data they protect?
  - Restricting access to personal information to active users and active user accounts?
  - Blocking access after multiple unsuccessful attempts to gain access?
- ✓ Do you have secure access control measures that restrict access, on a need-to-know basis, to personal information records and files?
- ✓ Do you assign unique identifications plus passwords (which are not vendor supplied default passwords) to each person with computer access; and are those IDs and passwords

reasonably designed to maintain the security of those access controls?

- ✓ Do you, to the extent technically feasible, encrypt all personal information records and files that are transmitted across public networks, and that are to be transmitted wirelessly?
- ✓ Do you, to the extent technically feasible, encrypt all personal information stored on laptops or other portable devices?
- ✓ Do you have monitoring in place to alert you to the occurrence of unauthorized use of or access to personal information?
- ✓ On any system that is connected to the Internet, do you have reasonably up-to-date firewall protection for files containing personal information; and operating system security patches to maintain the integrity of the personal information?
- ✓ Do you have reasonably up-to-date versions of system security agent software (including malware protection) and reasonably up-to-date security patches and virus definitions?
- ✓ Do you have in place training for employees on the proper use of your computer security system, and the importance of personal information security?

01CMR1700reg.pdf  
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<http://www.mass.gov/Eoca/docs/idtheft/2>

## CME Exam and Evaluation

### Physician Practices Scramble to Comply With the New Privacy Reg

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Please answer the following questions. A score of at least 70% is required to receive *1 AMA PRA Category 1 Credit™*. Deadline for completing the exam is August 23, 2011. Please make a copy for your records.

1. Solo practitioners are not required to develop a Written Information Security Plan (WISP).
  - a. True
  - b. False
2. The 201 CMR 17.00 standards apply only to electronic data.
  - a. True
  - b. False
3. Third party contractors must be in compliance with an organization's security system.
  - a. True
  - b. False
4. Penalties for noncompliance may range from \$100 to \$50,000.
  - a. True
  - b. False

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If yes, please explain.  
 \_\_\_\_\_  
 \_\_\_\_\_  
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# First suit filed over injury during robotic surgery

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daVinci.

But it is unlikely to be the last.

Angueira said that he has received a flood of phone calls – from plaintiffs' lawyers, patients and even physicians – with concerns about similar cases.

Manufactured by Intuitive Surgical in Sunnyvale, Calif., the daVinci is a robotic system with a 3D viewer for surgeons. The surgeon, who is seated, uses controls on a master console to maneuver the device's four robotic arms.

On its website, the company claims that the system is a major improvement over laparoscopic surgery because it gives surgeons an "immersive experience" that provides higher magnification, better dexterity and ergonomic improvements.

Patients benefit from a minimally invasive procedure and shorter hospital stays, according to the manufacturer.

But Angueira said that using the device requires extensive training and that some hospitals may be encouraging surgeons to use it before they are properly trained.

In Long's case, the doctors "basically told her they were going to perform this procedure [and] that they would be able to perform it in a less invasive manner," said Angueira. "More importantly, [they] never informed her that the physician who was doing it was in training and was being supervised by a different doctor."

Angueira said that he had been investigating the matter when an article in the Wall

Street Journal cited Long's case as one of several patient injuries at Wentworth-Douglass Hospital involving the daVinci robot.

Noreen Biehl, a spokeswoman for Wentworth-Douglass, a 178-bed community hospital, declined comment on the suit.

A statement on the hospital's website called the May 5 Wall Street Journal article "one-sided." It states that the hospital is "proud" of its "patient safety record with the daVinci robot and believes robotic surgery has extended the options for patients and actually created surgical treatments not available prior to its implementation."

It also says that the hospital's robotic surgery complication rates are lower than published rates.

## 'Huge area of concern'

Intuitive Surgical spokeswoman Nora DiStefano declined comment on the lawsuit.

James W. Saxton, a shareholder and chair of the health care litigation and risk management group at the Stevens & Lee law firm in Lancaster, Pa., said that manufacturers generally encourage hospitals to have stringent procedures in place to ensure that physicians who use their equipment are properly trained.

"They want their new products to be successful," he said. "The last thing they want is for there to be articles about potential problems and complications. In my experi-

ence, [manufacturers typically tell] the physicians and hospitals they are rolling this out with that they want the physicians to go through courses."

But Robert Hanscom, vice president of loss prevention and patient safety for CRICO/RMF, a Cambridge, Mass.-medical malpractice insurer and risk management foundation for Harvard Medical institutions, said that a lack of proper training with new medical technology is a "huge area of concern."

Hospitals must assess whether a physician is qualified to use new equipment, and "if not, whether they are going to get the training to assure everyone they can," Hanscom said.

"Some of the organizations have really taken that credentialing and privileging role very seriously as new equipment comes in, but others have been somewhat variable and inconsistent about it," Hanscom commented.

He said that he favors training physicians with computer simulation programs or mannequins so that surgeons can develop proficiency with new equipment "without the threat of injuring the patient."

However, health care providers sometimes start using new devices too quickly, Hanscom said.

"Everyone is pressured to ... get [a] new procedure up and running" or to implement a

"new clinical approach that everyone is talking about and [in some cases,] they haven't taken the time they need to assure they have the patient safety piece in place," he said.

## Unclear training standards?

David M. Gould, a medical malpractice defense lawyer and senior partner at Ficksman & Conley in Boston, said that credentialing and training standards for advanced medical technology vary from hospital to hospital.

"The problems have come about with the daVinci robots, as well as lasers," he said. "The inherent issues are the same with both, which is: What is the standard in training people to use this advanced equipment? I will tell you that there is none."

However, Gould said he is less concerned about the use of advanced technology at large, teaching hospitals, where credentialing standards are generally high.

"The problems are going to come in the community hospitals, where the numbers [of procedures] are smaller, and the practical experience of the surgeons who are operating at these facilities is much less," he said. **MMLR**

Questions or comments can be directed to the writer at: [nora.tooher@lawyersusaonline.com](mailto:nora.tooher@lawyersusaonline.com)



# HIPAA regulations create new burden for providers

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new limits on the disclosure of health information for fundraising purposes.

"The notices of privacy practices that are handed out to every patient and posted on the wall and on [a covered entity's] website will have to be revised to include [the] changes. ... It's just burdensome," said Fehn.

Entities will also have to update notices to allow patients to opt-out where allowed.

"It's a significant undertaking for the provider community," said Harlow.

"The changes are not required now. When the rules are finalized [a few] months from now, then there will be a timeline for compliance," he added.

## Warning: Policies are a must

The rules are a warning to the many health care providers that still don't have policies or have inadequate procedures for HIPAA compliance.

"I've seen a lot of providers' compliance manuals and they have one page about HIPAA," said Fehn.

She added that the agency that will enforce the rules, the Office of Civil Rights, will have less discretion than suggested in the past and will be more likely to impose penalties.

One area where covered entities often make mistakes is not fully addressing requirements for obtaining a patient's authorization.

"I still see a lot of authorization policies that

don't comply with all the requirements. [Health care providers] are still confused about when they need authorization. There are very specific requirements to have a valid authorization," said Fehn.

A typical error would be failing to specify the reason for disclosing protected health information or the person to whom it will be disclosed.

Health care lawyers said that the rules contain many helpful examples of how penalties will be assessed, but the main takeaway is that providers with policies in place are less likely to be harshly penalized.

"If you have compliance procedures in place and at least are making a good faith effort, but for some reason something goes wrong – like maybe an employee didn't do what he was supposed to do – that would fall within 'reasonable cause,' a lower penalty," said Fehn.

The penalties for privacy breaches are tiered based on "reasonableness" and "willfulness."

Violations resulting from a "reasonable cause" incur a \$1,000 penalty per violation, whereas violations due to "willful neglect" incur penalties of \$10,000 or \$50,000 minimum per violation, depending on whether the problem was corrected.

## Contract revisions galore

Agreements between covered entities and business associates must be reviewed and updated to comply with the new requirements.

The rules give providers who already have a business associate agreement 240 days from the date of a final rule to make the changes, and even those without an agreement have six months from the final rule's effective date to include HITECH provisions in the agreement.

"It benefits covered entities to get an agreement before the final rule," said Fehn.

A final rule is expected by this fall.

Covered entities should also consider going further than the contract and make sure their business associates have HITECH policies and procedures in place.

"In the past simply having an agreement in place with a business associate was enough. Now it's incumbent on covered entities to engage in auditing business associates for their policies and operations. The alternative is potential exposure to significant liability," said Harlow.

He added that the statute allows state attorneys general to sue for civil damages on behalf of individuals whose privacy is breached.

Even though business associates are independently liable, a breach of protected health information by a business associate is imputed to the covered entity under breach notification requirements. The covered entity has 60 days to report a breach from the time a business associate discovers the breach, even if the business associate doesn't act.

One contract revision would be to include an indemnity provision in such a case.

"To the extent a covered entity is liable for a business associate dropping the ball, the covered entity would want to cover the cost," said Elizabeth Litten, a partner at Fox Rothschild in Princeton, N.J.

Another contract provision might cover which party is responsible for determining if a breach has occurred.

The statute allows an exception to breach notification requirements if the breach carries no risk of harm.

"In some instances, the covered entity wants to make that determination even if the potential breach was made by the business associate. Other [contracts] might ask the business associate to decide and take full responsibility," said Litten.

The fact that the rules now clarify that subcontractors of business associates are essentially treated as business associates themselves means that contracts between business associates and the companies they contract with must also be reviewed.

"Anything that would be in the business associate agreement or anything where there is a direct obligation pursuant to HITECH is now pertinent to subcontractors," said Litten. **MMLR**

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