

Hospitals fight off infections and lawsuits

By Sylvia Hsieh

Several recent developments indicate that hospitals may face increasing liability for infections that patients acquire in the hospital.

On Nov. 6, a Suffolk County jury awarded \$13.5 million to a 40-year-old Hopkinton woman who died of a flesh-eating bacteria that she contracted during chemotherapy treatment at Dana-Farber Cancer Institute.

A number of new state and federal rules will also change the liability landscape for hospitals:

- State regulators unanimously approved a regulation requiring Massachusetts acute care hospitals to report hospital-acquired infections, which the state Department of Public Health will make public online. Health care facilities are required to register for the surveillance system by April 1, with data collection set to begin July 1.
- As of Oct. 1, 2008, Medicare has stopped reimbursing for certain types of hospital-acquired infections.
- The Centers for Disease Control and Prevention recently published guidelines for preventing infections.
- In October, The Joint Commission, which accredits hospitals and health care programs, released a compendium of recommendations for preventing hospital-acquired infections.

'Inviting lawsuits'

The focus on prevention puts a new onus on health care providers.

The CDC has estimated that over 2 mil-

Continued on page 10

All eyes on B.I.?

The SEIU's latest tactic in organizing health care workers hits Beth Israel

By Bill Ibelle

During a recent fundraising event for Beth Israel Deaconess Medical Center, a flatbed truck pulled up out front carrying a mobile billboard inscribed with three-foot red letters – "Keep Your Eye on B.I."

The billboard advertised a website of the same name, www.eyeonbi.org, that alleges serious problems with patient care

and accounting practices at the hospital.

It was paid for by the Service Employees International Union (SEIU), which is hoping to organize service workers at Boston area hospitals.

According to Beth Israel CEO Paul Levy, the billboard and website are part of a "corporate campaign," a new union strategy that shifts the initial portion of a union drive from the traditional task of organiz-

ing workers to undermining the target organization's credibility with key constituents who are critical to its survival.

"The object at this point is to degrade [the hospital's] reputation in the community, in the hope of getting concessions in the certification process [for union elections]," Levy said in his blog, runningahospital.blogspot.com.

"There may also be an interest in showing other hospitals in Boston what the union can do if it wants to spend money trying to hurt your reputation," he went on to write. "Beyond the mobile billboard, SEIU has spent tens of thousands of dollars in just one month on misleading advertising at bus stops, on radio, and on television about topics that have little or nothing to do with workers' concerns."

The union, meanwhile, insists that the purpose of its Eye on B.I. campaign is to promote quality patient care.

"Our number one goal is to get the hospital reoriented back to its basic mission of serving the needs of the patients and the community," said Mike Fatal, Executive Vice President of SEIU local 1199. "There are lots of troubling practices at Beth Israel that call out for attention, and the purpose of the Eye on B.I. campaign is to shine a light and inspire action and accountability across the city."

Continued on page 5



Doctors must prepare now for new identity theft rules

By Sylvia Hsieh

Under new federal "red flag" rules, health care entities and physicians will be required to implement procedures for preventing, detecting and responding to identity theft, according to attorneys.

Until recently, many entities, including health care providers, thought the red flag rules only applied to traditional financial institutions, such as banks.

"Many in the health care industry were taken by surprise and are saying 'Wow,

they actually mean us,'" said Brent Eller, a partner in the health law practice group at Davis Wright & Tremaine in Seattle.

But the new rules also apply to "creditors" – a term that the Federal Trade Commission has interpreted broadly to include any entity that regularly extends credit or accepts deferred payment for services.

"The definition of creditor is enormous," said Pamela Devata, a management attorney at Seyfarth Shaw in Chicago.

The American Medical Association has written a letter to the chairman of the Fed-

eral Trade Commission, arguing that physicians shouldn't be covered by the rules.

The Federal Trade Commission extended the deadline for compliance from Nov. 1, 2008 to May 1, 2009.

Lawyers are advising health care providers not to wait for an answer from the FTC and to start implementing red flag procedures now.

"The safest course of action is to assume for now that the red flag rules will apply to most health care providers, regardless of their size, unless they require payment in full at the time of service," said Eller.

Martie Ross, a partner and health care attorney at Lathrop & Gage in Kansas City, Mo. agreed.

"I would not operate on the assumption these rules are going away," said Ross. "I would operate on the assumption that you've got six months to get your house in order."

The deadline extension is limited to the red flag rules for financial institutions and creditors.

Starting Nov. 1, users of consumer reports, including for extension of credit or

Continued on page 12

INSIDE

EARN CME CREDITS

New e-prescribing regulations applauded by doctors, lawyerspage 13

R^{EX} EXCELLENCE

honoring best practices in medicine

Check out photos from the awards celebration inside.page 7



DOCTOR'S RX:

A response to the Massachusetts Medical Society's Defensive Medicine Report 2008page 9

My health plan transformation

Over more than a decade of choosing health plans, my primary criterion has been the ability to go to any doctor without a referral.

My next round of concerns involved such things as the cost of premiums, what services were covered and the like.

While I have written multiple articles for lawyers on the benefits of Health Savings Accounts (HSAs) and their associated high deductible health plan requirement, the four-digit deductible always scared me away. Until now.



With the help of some savvy colleagues – and a shocking analysis of how much my family paid in premiums and co-insurance in the first 10 months of 2008 alone – I learned we would have saved a whopping \$2,500 had we selected the high deductible option. I was stunned.

In the face of such potential savings, the change was a no-brainer for me. I am hopeful that it will work in my favor, and won't mean hours of paperwork. Please stay tuned to see how it goes.

Of course, I am not alone when it comes to trying to cut expenses right now, and it's no surprise that cost concerns infiltrated the health care field well before the more recent downturn.

The big question remains: How can we contain health care costs without compromising quality? It's an issue that's going to become even more important in the year ahead.

The major source of the cost-containment problem, says Dr. Alan C. Woodward, who wrote our Doctor's Rx column on page 9, is our current tort system and how it deals with medical liability.

He cites a recent Massachusetts Medical Society study, which found that "defensive medicine" – where physicians make decisions about patients because they are afraid of being sued – is pervasive in the Commonwealth. The cost of these practices, in part, was conservatively estimated at \$1.4 billion, he notes.

How can we improve the situation?

Woodward calls for a transformation that's far bigger than one family changing its health insurance plan. You can read about his ideas on page 9, and see what some other experts think on page 8.

As we look ahead to 2009, the medical community should undoubtedly be thinking about changes that could reduce costs and increase efficiency, while at the same time improving the quality of the care we deliver in Massachusetts.

While people like me may love additional costs savings when it comes to health care (more money to spend on things like my toddler's diapers!), what we need more is the knowledge that the *quality* of our health care is top-notch.

Reni Gertner, MPH

Editor's Note

Table of contents

3 Regulatory compliance

'Through a glass, Starkly': CMS changes the Stark Law

4 Listening In



The news beat of the medical profession

6 Verdicts & Settlements

7 MMLR's Rx for Excellence Awards



Photos of our Oct. 31 awards celebration

8 Good Medicine

Q&A: Should our medical liability system be transformed?

9 Doctor's Rx

The time has come for liability reform

11 Bills, Rules & Regs

13 Earn CME Credits

Topic: E-prescribing

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Congratulations to Steven Schachter, M.D. and William Mandell, Esq. on being selected as "Heroes from the Field" by Massachusetts Medical Law Report and for the publication of Managing Relationships with Industry: A Physician's Compliance Manual, co-authored with Scott Harshbarger, Esq. and Professor Randall Grometstein, J.D., PhD.

For more book information see:
www.piercemandell.com/purchase.html

'Through a glass, Starkly': CMS changes the Stark Law

By William M. Mandell, Esq.
and Emily B. Kretchmer, Esq.

In *The Da Vinci Code*, the hero, Professor Robert Langdon, attempts to solve the murder of the curator of the Louvre Museum by interpreting cryptic messages and other mysterious clues.

One often seems to need Langdon's extraordinary problem-solving talents to decipher the Stark Law, and the most recent changes to Stark make this effort even more complex.

The Stark Law's complexity reflects the old adage of the exceptions swallowing the rule.

Stark prohibits a physician from referring patients for certain Medicare and Medicaid services to any entity that has a financial relationship with that physician, or a member of his or her immediate family.

It also prohibits an entity receiving a prohibited referral from billing Medicare or Medicaid for that referred item or service.

Congress understood back in 1991, when the Stark Law was passed, that such a broad prohibition necessitated several exceptions, and gave broad discretion to the Centers for Medicare and Medicaid Services (CMS) to issue rules clarifying its scope.

Unlike federal and state anti-kickback laws, Stark is a "zero tolerance" law.

Stark applies to the referral of all inpatient and outpatient hospital services, so virtually all physician-hospital relationships must fall within a Stark exception.

Stark also applies to the financial relationships between physicians and medical practices that offer ancillary services, and any other providers with whom they have financial relationships and refer Stark covered services or items, such as clinical lab or radiology.

For more information about the Stark Law before the changes discussed in this article, you can download "Making Sense of the Stark Law" at: <http://piercemandell.com/publications.html>

Phase III changes

Over the last 17 years, CMS has wrestled with this mandate.

After the 1992 effective date of the Stark Law, it took the agency over three years to issue the first set of rules in 1995.

Over the next 12 years CMS issued two more sets of rules and comments, often completely reversing its own rules.

The latest installment, Phase III, became effective on Dec. 4, 2007.

The key changes under Phase III that remain in effect are:

- A group practice must contract directly with independent contractor physicians.
- Revenue from "incident to" services, other than diagnostic tests, can be allocated directly to a physician's bonus.
- Recruitment rules became more flexible.
- The fair market value hourly rate safe harbor for contracted physician services was eliminated.
- Health care providers have a six-month holdover period to renew and renegotiate expired space or equipment leases and

Bill Mandell is a shareholder and Emily Kretchmer is an associate with the law firm, Pierce & Mandell, P.C. They represent physicians, medical practices, hospitals and other providers with health and business law matters, including Stark and anti-kickback compliance.



Mandell



Kretchmer

contracts for personal service arrangements.

To read more details about the Stark Phase III rules, see "Doctors urged to review referral practices," Massachusetts Medical Law Report, Winter 2008. Search terms for mamedicalaw.com: Stark and referral.

Latest changes

In a relatively sudden burst of action in 2008, CMS further changed Stark in the 2008 physician fee schedule ("PFS") and the 2009 inpatient prospective payment system ("IPPS") final rule.

Here are some of the major changes under those rules.

'Stand in the shoes' rule

Under the 2009 IPPS final rule, as of Oct. 1, 2008, CMS considers physician owners to

"stand in the shoes" of their group practice organizations.

For Stark purposes, that means physician owners now have direct compensation relationships with any entities that remunerate their group practices in any way.

However, physicians employed by practice entities affiliated with academic medical centers or non-profit health care delivery systems are not subject to this rule. Physicians who hold a titular ownership interest in such entities (such as a physician member of a non-profit corporation) are also exempt.

CMS drew this distinction to avoid prohibiting non-profit hospitals from providing working capital funds to their affiliated medical groups.

Services provided 'under arrangement'

Also under the 2009 IPPS final rule, CMS has expanded the definition of "entity" un-

der Stark to include the person or entity that performs the services, even if another party actually bills for them.

This change goes into effect on Oct. 1, 2009.

It will effectively convert the relationship of any group practice or joint venture that provides inpatient and/or outpatient services "under arrangement" with a hospital from an indirect to a direct relationship.

This means that a physician won't be able to own any part of an entity that provides services under arrangement to hospitals except for (1) rural hospitals, (2) entities owned by radiologists, radiation oncologists or pathologists, and (3) lithotripsy arrangements.

Despite this expanded definition, hospitals may be able to maintain an "under arrangement" relationship with an organization that is not owned by physicians but has a compensation relationship with physi-

Continued on page 15



MARCH 5, 10:40 AM

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

MAY 23, 12:00 PM

Investigators from the Inspector General's office arrive, unannounced, at your office to interview you and your staff.

MAY 23, 12:05 PM

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Listening In

The news beat
of the medical profession

Health plans expect economic trouble to last

Health plans' profits are on the decline and executives at many plans say they don't expect that trend to reverse itself soon, according to American Medical News.

The falling earnings are giving rise to speculation that a few plans might put themselves up for sale, leading to further industry consolidation.

Many plans focused on warning investors – as WellPoint and United HealthGroup did even before third-quarter earnings reports were issued – not to expect the profit growth of the past.

Wall Street is reacting to the plans' warnings by hammering stock prices. The only plans that didn't reach their 52-week low on the day of the earnings release were WellPoint and United, which reached that level when they issued their earlier warnings, AM-News reported.

New study monitors 'never events' liability

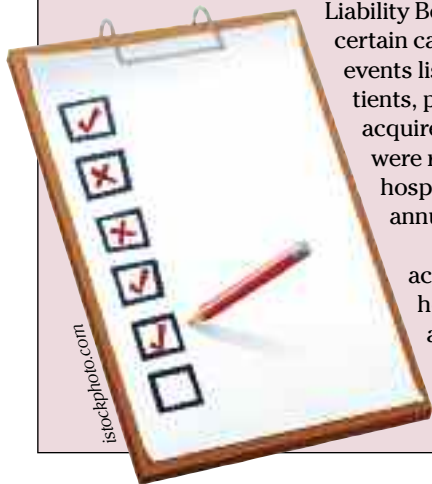
So-called "never events" accounted for one in six medical liability claims filed against hospitals in 2007, according to a recent study, American Medical News reported.

"Never events" are 28 serious adverse results that should never happen, according to the National Quality Forum.

On Oct. 1, the Centers for Medicare & Medicaid Services stopped reimbursement for 10 hospital-acquired infections it has termed never events.

Aon Corp.'s 2008 Hospital Professional Liability and Physician Liability Benchmark Analysis found that certain categories from the never events list – objects left in surgical patients, pressure ulcers, and hospital-acquired infections and injuries – were responsible for 12.2 percent of hospitals' total liability expenses annually.

A number of recent verdicts across the country have found hospitals negligent for hospital-acquired infections. (See "Hospitals fight infections and lawsuits" on page 1.)



Doctor networking site in investor access deal

Sermo Inc. of Cambridge, which operates an Internet social networking site for physicians, has struck a deal with financial news provider Bloomberg LP that will give professional investors access to Sermo, according to the Boston Globe.

Investors will be able to communicate with Sermo's 90,000 users and get information about promising drugs and medical devices directly from the doctors who use them.

Sermo chief executive officer Daniel Palestrant said the new service will help doctors influence investments in health care companies, while helping investors make better-informed decisions.



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Court upholds ban on drug data mining

A federal appeals court upheld a New Hampshire law prohibiting data miners from tracking physicians' prescription history in an effort by pharmaceutical companies to market drugs more effectively.

"In the service of maximizing drug sales, [pharmaceutical marketers] use prescribing histories as a means of targeting potential customers more precisely and as a tool for tipping the balance of bargaining power in their favor," wrote Judge Bruce M. Selya for the majority of the U.S. Court of Appeals for the 1st Circuit. "As such, detailing affects physician behavior and in-

creases the likelihood that physicians will prescribe the [marketers'] (more expensive) drugs."

In July 2008, Massachusetts lawmakers attempted to pass a similar provision during debate over a cost-control bill. The provision was stripped out during final negotiations between the House and Senate.

Officials at Pharmaceutical Research and Manufacturers of America argued to the court that using marketing data is protected under the constitutional right to free speech and that their efforts help doctors make more informed prescription choices.

New banking services for physicians

Physicians Insurance Agency of Massachusetts (PIAM), a subsidiary of the Massachusetts Medical Society, is now offering its members access to Boston Private Bank & Trust Company's private banking services.

PIAM members, their families and their medical practices can take advantage of four key offerings of Boston Private Bank: deposit and cash management, residential lending, investment management and trust services and commercial banking.

"The PIAM and Boston Private Bank relationship presents a great opportunity for practices to reeval-

uate their current banking relationships, especially in the current economy," said Jack King, the president of PIAM, in a statement. "Physicians and their families now have the opportunity to work with a private bank that has built its reputation on exceptional client service, access to senior-level decision makers, customized financial solutions, responsiveness and expertise, as well as strength and stability in an otherwise volatile marketplace."

Practices interested in learning more about Boston Private Bank & Trust Company should call PIAM at (800) 522-7426 or go to <http://piam.bostonprivatebank.com>.

Suit: Doctor, hospital covered up operation

Barbara Circiello is suing Hallmark Health Systems, Inc. and Louis Alfano, Jr., M.D. for \$10 million, claiming they violated the federal Racketeer Influenced and Corrupt Organizations Act, known as RICO.

RICO provides penalties for fraudulent acts performed as part of an illegal enterprise.

Circiello claims that the cause of her father's death was uncontrolled bleeding resulting from an unnecessary and incompetently performed operation.

Further, she contends the defendants actively covered up their mistakes.

Circiello alleges that a criminal enterprise consisting of Alfano's father, a corporation estab-

lished by the Alfano family, Melrose Wakefield Hospital, a surgeon who provided "expert" medical opinions in Alfano's defense and Alfano's insurance carrier collectively defrauded her by leading her to believe that her father died of natural causes.

As a result of the alleged cover-up, too much time has elapsed for the patient's family to file a malpractice suit. The Board of Registration in Medicine has investigated and sanctioned the doctor.

This is believed to be the first time that a civil RICO case has been brought against a doctor and hospital in Massachusetts.



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All eyes on B.I.?

Continued from page 1

When asked directly whether the union hoped to unionize workers at Beth Israel or other area hospitals, Fatal sidestepped the question, saying that the union's primary purpose is to promote quality care and "a health care system that works for everyone."

The 'corporate campaign'

It is no mystery that the SEIU sees Boston hospitals as a fertile ground for union organizing.

But so far, the union has made no direct attempts to win workers' support at Beth Israel or other area hospitals.

Instead, it has spent millions of dollars attacking the hospital administration for, in Fatal's words, "practicing a corporate style of medicine rather than focusing on the patients and the community."

From Levy's perspective, the campaign is a highly sophisticated way to gain a negotiating edge before the union drive begins.

He contends that the goal is to cast doubt on the hospital's credibility among donors, legislators, regulators, patients and – almost incidentally at this point – among the workers themselves.

The union's hope, Levy has said, is to weaken the hospital to the point where it will make major concessions in return for the union's agreement to call off its plans to organize the hospital's workers.

Fatal does not like to characterize the union's actions as being part of a "corporate campaign."



How hospitals can respond

The charges against Beth Israel Deaconess Medical Center detailed on the Eye on B.I. website are serious – overworked surgical interns, financial discrepancies, attacks on workers' rights, inadequate charitable care as well as poor pay and poor working conditions.

Whether or not these charges are valid, the Boston medical community needs to prepare itself for a new kind of union organizing.

"Any forward-thinking health care organization that thinks it could be targeted needs to be preparing for this," said Ashley McCown, president of the crisis management firm, Solomon McCown & Co. "Don't let the union define you as an organization. You need to communicate first."

Since the goal of the union's campaign is to undermine the hospital's reputation with key constituencies, McCown said hospitals should review their vulnerabilities before a campaign begins.

Areas that are likely to become a union target include:

• CEO compensation.

Given the focus on CEO salaries amidst the current economic collapse, pay scales for top hospital executives are virtually guaran-

teed to be an issue during any negative publicity campaign, experts say.

• Malpractice and employment lawsuits.

McCown noted that virtually every hospital is vulnerable on the issue of malpractice suits and patient complaints.

"They need to have a message ready for when the union publicizes malpractice suits and patient complaints," she warned. "They need to put those complaints in context and have a program up and running to address those concerns and bring improvement."

• Real estate development and expansion plans.

Union organizers "will try to undermine the hospital's credibility among legislators and permitting boards," said McCown. "The best-known example of this was Yale/New Haven Hospital several years ago, when it was trying to build a new cancer treatment unit and needed state approval. SEIU held up the permitting process and launched an ad campaign targeting the hospital. It was a long, bloody corporate campaign."

• Employee relations.

"Hospitals need to make sure they have

open and direct communication with their employees – and make sure those connections are real," said McCown. "They need to look honestly at the work environment and culture. If those relationships are not strong, they need to respond to that weakness *before* they are the target of a campaign."

Hospitals also need to be sure they are getting the message out about the good things they are doing in the community.

"If they have been doing community work and conducting education programs, they need to make their key constituencies – legislators, regulators, donors, the general public and the staff – are aware of these efforts," she said.

McCown notes that Levy has been extremely proactive in his attempts to counter the union's characterization of the hospital as a patients-last institution.

In his blog, he includes dozens of e-mails from employees, interns and doctors from both inside and outside the hospital praising the working conditions at Beth Israel and expressing grave concerns about SEIU.

"Hospitals should start on the inside and work their way out," said McCown. "It all begins with the employees." **MMLR**

– Bill Ibelle

The union prefers to characterize it as a "social accountability campaign" or a "quality care campaign." Regardless, the objective is to portray the hospital as an institution that puts profits ahead of patient care.

The Massachusetts Hospital Association, while emphasizing that it takes no position

on unionization and supports the right of workers to self-determination, expressed concern about the current trend in union tactics.

"The MHA is concerned about the negative impact of union-sponsored corporate campaigns which serve only to damage hos-

pital reputations and jeopardize the core mission of hospitals to care for patients and their community," said hospital association CEO Lynn Nicholas. **MMLR**

Questions or comments should be directed to the editor at: reni.gertner@mamedicallaw.com



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We offer our congratulations to all the winners of the 2008 Massachusetts Medical Law Report Leaders in Quality. We are honored that four of our own have been selected among the best and the brightest of the Bay State's world-class health industry. Their expertise and commitment exemplifies the best in health care.

Verdicts & Settlements

Cancer patient wins \$13.5M

The family of a 40-year-old Hopkinton woman who died after a cycle of experimental chemotherapy at the Dana-Farber Cancer Institute in Boston was awarded \$13.5 million by a Suffolk Superior Court jury, according to The Boston Globe.

The jurors decided that Amy Altman's death could have been prevented if Dana-Farber physicians had investigated the cause of chronic diarrhea that surfaced during an unusual treatment protocol for a tumor behind her knee, said Robert M. Higgins, the plaintiff's lawyer.

Altman's complaints about the diarrhea were dismissed as an expected side effect in separate consultations with two Dana-Farber oncologists, Dr. Suzanne George and Dr. Jeffrey Morgan, Higgins said.

Altman soon began suffering extreme abdominal pain and could not urinate. She died less than two days after being admit-

Hospital found liable in 2001 patient attack

A jury found that negligence on the part of Brockton Hospital caused an elderly patient to be assaulted with a commode by another patient in 2001, according to the Enterprise.

The victim, James A. Matthews of Whitman, was 86 when he was attacked and seriously injured by an over-medicated hospital roommate, according to the lawsuit.

Matthews filed the suit against Brockton Hospital in 2002. He died the next year, but his wife, Maizie, continued as a plaintiff in

the case.

A jury awarded the 90-year-old Whitman woman \$45,000 in damages following a three-day trial in Plymouth County Superior Court.

The lawsuit did not target the assailant in the case, a 65-year-old male patient. Instead, the suit accused the hospital of over-medication with narcotics and then failing to act when he showed signs of severe agitation and delirium.

Over a 14-hour period, the patient grew

increasingly agitated and paranoid, but neither he nor Matthews was moved to a separate room, according to the widow's attorney, John F. Danehey of Scituate.

Finally the patient "exploded," picking up a commode and throwing it at Matthews, who had been sitting on a bed looking out the window, Danehey said.

The hospital took no responsibility for the assault and charged Matthews several thousand dollars for the resulting required CT scans and X-rays, Danehey said.

ted to Brigham and Women's Hospital for a massive infection caused by flesh-eating bacteria that apparently had caused the diarrhea, the Globe reported.

The autopsy found that the cancer had been cured, Higgins said.

Dana-Farber itself was not included as a defendant, said Higgins, a medical malpractice lawyer at Lubin & Meyer in Boston.

Surgical screws left inside patient

In March 2002, a 49-year-old woman with a history of scoliosis underwent spinal fusion with instrumentation by the defendant.

Before the operation, her symptoms were limited to low back pain and left leg pain. After the surgery, she was found to have a profound left-foot drop with numbness and reduced sensation.

Despite these symptoms, the defendant failed to investigate to determine whether there may have been misplaced instrumentation.

The patient underwent a lumbar CT scan three months after her surgery that demonstrated misplaced pedicular screws, which encroached on several nerve roots. Despite these abnormal findings, the defendant failed

to bring the patient back to the operating room for corrective surgery.

Approximately two years later, the patient went to a new orthopedic surgeon, who brought her back to the operating room for a complete revision and replacement of all of the spinal hardware.

The fusion, which had previously been at two levels, was extended to four levels.

The patient obtained significant relief from the three-stage corrective surgery. However, she was left with a mild left-foot drop and persistent pain in the left leg and foot.

The case settled for \$800,000.

Type of action: Medical malpractice

Injuries alleged: Permanent nerve damage with foot drop

Date: April 2008

Submitted by: Marc L. Breakstone, Breakstone, White & Gluck, Boston (for the patient)

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 both health care providers and plaintiffs, in addition to settlements.

If you have an item you would like to submit, please contact Matt Yas at matt.yas@lawyersweekly.com or 617-218-8152.



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MASSACHUSETTS MEDICAL LAW REPORT'S RX FOR EXCELLENCE AWARDS

celebrated 40 individuals and establishments across Massachusetts that have demonstrated the highest standards of safety, quality and risk management. Top professionals gathered for breakfast at the Taj Boston on Oct. 31 to celebrate their accomplishments. We honored the winners with two kinds of awards. The Heroes from the Field are the unsung heroes of their profession; those who lead by example, demonstrating the highest quality of work in their field, often without fanfare. The Leaders in Quality are the professionals and institutions that have enacted broad changes to advance safety, quality and risk management for patients and providers.



All are from left. **1.** Reni Gertner, MPH, MMLR; Luis Sanchez, M.D., Physicians Health Services, Inc. **2.** David Dykeman, Esq., Greenberg Traurig; George LeMaitre M.D., LeMaitre Vascular; Cornelia LeMaitre; Kathleen LeMaitre. **3.** Scott Harshbarger, Esq., Proskauer Rose. **4.** Paul Donaghue, Esq., Law Offices of Paul Donaghue; Pam Kaiser, HealthBridge Management; Nancy LaRock, Life Care. **5.** Awards. **6.** MMLR Publisher David Yas congratulates award recipient George Blackburn, M.D. **7.** Jennifer Ryan Brown; Ken Brown; Doug Brown, Esq., Cheryl Lapriore, and John O'Brien, UMass Memorial Health Care. **8.** Michael Schachter; Reni Gertner; William Mandell, Esq., Pierce & Mandell, P.C. **9.** Guests from ProMutual Group watch as honorees receive their awards. **10.** Nancy Otovic, M.D., Lahey Clinic; Reni Gertner. **11.** Paula Griswold, Massachusetts Coalition for the Prevention of Medical Errors; Roseanna Means M.D., Women of Means, Inc.; Mary Lou Ashur, M.D., Caritas Carney Hospital; Michael Miller, M.D., HealthPolCom Consulting; Amy Rosen, PhD, Boston University School of Public Health. **12.** Andrew Eisenhauer, M.D., Brigham and Women's Hospital; Allan Goroll, M.D., Massachusetts General Hospital; Bill Bailey-Eisenhauer, Immunogen. **13.** Debra Grossbaum, Physician Health Services Inc.; Vincent DiCianni, Esq., Affiliated Monitors Inc. **14.** Lena Deter, RN MPH, Hebrew SeniorLife; John Deter, Hebrew Rehabilitation Center; Bill Glowik, Arjo, Inc. **15.** Dick Brewer, Maureen Mondor, Anne Huben-Kearney and Nina Akerley of ProMutual Group. **16.** Bruce Cohen, M.D., Bolton Family Medicine; David Yas. **17.** Cheryl Lapriore, UMass Memorial Health Care; Ken Brown.

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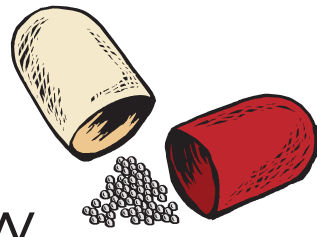
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Good Medicine



What doctors are talking about now

Q: Should the medical liability system be transformed into a new model that emphasizes safety, avoidable error, injury compensation and alternative dispute resolution?

“A more enlightened approach to medical liability would distinguish providers who generally drive toward quality improvement and safety. The potential for those providers to opt into a different compensation system would have the dual effect of treating patients and providers fairly while creating an incentive to become eligible for the ‘opt-in’ system. The new model ought to incorporate three salient features: a trustworthy evaluation to certify the provider infrastructure; transparent quality performance reporting; and a closed clearinghouse – not available to plaintiffs – to which providers in the alternative system must report what they have learned from circumstances that created harm.”

—Alice Gosfield, Esq., health lawyer, Philadelphia, Pa., represents physicians and group practices



“Changes in the medical liability system need to originate at the provider/institutional level, such as the system adopted by the University of Michigan Health System, whose approach is: ‘Apologize and learn when we’re wrong, explain and vigorously defend when we’re right, and view court as a last resort.’ Any changes should consider early non-binding evaluation by neutrals; reject caps for non-economic damages; adjust or eliminate the charitable immunity cap; and provide a more efficient, cost-effective method for resolving smaller claims.”

—Robert H. Astor, Esq., plaintiffs’ attorney, Springfield



“Studies about defensive medicine and the suggestion that there is a medical malpractice crisis shift the focus away from where it really belongs: the victims for whom medical error has been a life-changing event. A trial by jury is usually the last resort for those victims of medical error for whom justice is not offered or available. We should all strive for the day when medical errors are rare, readily acknowledged and victims are fairly compensated. For the foreseeable future, the trial court and jury system and the level playing field that they afford are many people’s last hope and only opportunity for justice.”

—Kimberly Winter, partner at White, Freeman & Winter, Weston, handles medical negligence cases and provider licensure.



“My approach to reforming the system would include: (1) a tribunal system more in keeping with the legislative intent, rather than a system that allows the plaintiff to get by so long as she presents a medical opinion letter; (2) a requirement that the defendant be notified 90 days before a suit is filed; (3) encouragement of open discussion of unfavorable medical outcomes by providing that ‘apologies’ be inadmissible in court; (4) limitation of recovery against an individual physician to her insurance limits; (5) requiring that experts be board-certified in the same specialty as the defendant; and (5) a medical malpractice court with specialized judges.”

—John Bagley, partner at Morrison Mahoney, Springfield; represents physicians



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The time has come for liability reform

By Alan C. Woodward, M.D.

Medical liability in Massachusetts has become an extraordinary burden on our health care system.

It produces years of litigation, financial inefficiencies, a culture of secrecy and a "blame game" mentality, plus unaffordable premiums for physicians. It is dysfunctional for physicians and patients.

Harvard School of Public Health Professor Michelle Mello has described it aptly: "For compensation, deterrence, corrective justice, efficiency and collateral effects, the system gets low or failing grades."

The latest indication of the system's failings comes from a survey of Massachusetts physicians about the practice of defensive medicine: tests, imaging, referrals, consultations and hospitalizations ordered by physicians out of the fear of being sued.

The survey is the first of its kind to quantify defensive practices across a wide spectrum and among a number of specialties, as well as the first to link such data directly with Medicare cost data.

The study, conducted by the Massachusetts Medical Society, found that 83 percent of physicians reported practicing defensive medicine and that an average of 18-28 percent of tests, procedures, referrals and consultations and 13 percent of hospitalizations were ordered for defensive reasons. The costs of these practices, in part, were conservatively estimated at \$1.4 billion.

But that number falls short of the real costs: the survey queried physicians in just eight specialties, accounting for only 46 percent of the physicians in the state.

The estimate doesn't include tests and procedures ordered by physicians in other specialties and it doesn't account for observation admissions to hospitals, specialty referrals and consultations or unnecessary prescriptions.

Reduced access to care, through the avoidance of high-risk procedures and high-risk patients, is another concern.

The survey found that 38 percent of physicians reduced the number of high-risk services they perform and that 28 percent reduced the number of high-risk patients they serve. These findings are similar to previous studies. Over a five-year period, MMS workforce studies have found an average of 44-48 percent of physicians saying they alter or limit services due to the fear of litigation.

Defensive medicine also raises safety issues: Patients exposed to unnecessary imaging face the risks of radiation exposure, and many surgical procedures, such as Caesarean sections (now estimated to be one in three births), have increased as a result of liability concerns.

Threatening landscape

Clearly, defensive medicine carries huge costs, reduces access to care, and poses unnecessary risks.

Yet it remains widespread because the fear of being sued, with its potentially dire economic, personal and professional consequences, is so pervasive.

Recent decisions from the Massachusetts Supreme Judicial Court create an even more threatening landscape.

The case of *Coombes v. Florio*, extending the possibility of physician liability to a third party outside of the doctor-patient relationship, and *Matsuyama v. Birnbaum* and *Renzi v. Paredes*, permitting recovery for a "loss of chance" for a better medical outcome, may signal more lawsuits and create more defensive medicine.

The irony is that at the same time the Commonwealth has become a model for health care reform, it has widened the liability of all physicians.

As the state struggles with exploding costs – which experts agree is the biggest threat to the success of reform – it is seeing billions spent on defensive medicine.

Reform is long overdue. A new model is needed that enhances patient safety; encourages open communication, full disclosure and transparency; offers sincere apologies for avoidable injuries with a proposal for timely and fair compensation; and resolves disputes with mediation and arbitration. Lawsuits should be a last resort.

Such a model – like the one proposed by The Joint Commission – compensates more patients more quickly and equitably, while dramatically reducing litigation and restoring trust among all parties.

This approach fundamentally transforms the system from reactive to proactive, from adversarial to advocacy-based, from a culture that isolates patients and providers to one that supports them, from a system that thwarts safety to one that embraces it, and from one that encourages defensive medicine to one that promotes evidence-based medicine.

Progress has occurred. Harvard University's 2005 Consensus Statement of "When Things Go Wrong: Responding to Adverse Events" was a

giant first step toward sound policies and practices in this state. Apology legislation, already passed in many other states, is gaining interest in the Commonwealth.

With spiraling costs, reduced access, and the threat to our state's health care reform, how much longer can we afford to wait?

Physicians, lawyers, insurers, legislators, policymakers and patients must come together to start the dialogue and process of reform.

Alan C. Woodward, M.D., is a past president of the Massachusetts Medical Society and Vice Chair of its Committee on Professional Liability.

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Hospitals fight off infections and lawsuits

Continued from page 1

lion hospital-acquired infections occur annually, resulting in 90,000 deaths. In long-term care facilities, the CDC estimates that an additional 1.5 million health-care associated infections occur each year.

The goal of the Massachusetts reporting requirement is to help eliminate hospital-acquired infections completely by 2012, according to the State House News Service.

"It's a rapidly changing environment. Now that the evidence is overwhelming that nearly all infections are preventable, hospitals that don't follow the proven protocols are inviting lawsuits," said Betsy McCaughy, founder and chair of the Committee to Reduce Infection Deaths, a non-profit patient safety organization in New York.

"Anyone providing health care to an individual is no longer going to have immunity for transmitting infections," said Gloria Seidule, an attorney at Seidule & Webber in Stuart, Fla. who is currently litigating a hospital-acquired infection lawsuit involving Methicillin Resistant Staph Aureus (MRSA), a "superbug" that is resistant to most antibiotics and accounts for over 50 percent of staph infections.

Mary Coffey, an attorney at Coffey Nichols in St. Louis, Mo., said "the standard of care is changing."

"There are CDC standards on infection prevention and lots of published materials that can be used to establish the standard of care," she said.

Coffey recently won a \$2.58 million verdict for a 69 year-old man who contracted MRSA through an IV that was administered in the



ambulance following a heart attack. When doctors inserted a pacemaker, the infection spread, ultimately resulting in the loss of a kidney and a leg.

Seidule said that hospitals in general have not taken the initiative on prevention measures.

"The CDC issued guidelines in 2007 but this knowledge has been around since 1999. Only recently have hospitals even begun to

institute the types of control measures to prevent the spread of infections," she said.

What hospitals can do

There are a number of simple steps hospitals can take to prevent infections.

Some of them are low-tech, like washing hands and training clinicians on preventing recontamination by not opening the privacy curtain once they are in surgical gloves, said McCaughy.

The most effective prevention initiatives are geared toward creating a culture of improving the quality of care, said Eric Booth, chief operating officer of The Leap Frog, a patient advocacy organization in Washington, D.C.

For instance, he said that when a hospital-acquired infection occurs, it's important for hospitals to conduct an evaluation to determine how it happened.

"Everyone involved in the patient's care, including doctors, nurses, aides and all ancillary care givers should be involved in the discussion post-incident to discuss in an open forum without risk of penalization what occurred and how to prevent it in the future," Booth said.

He also suggested that hospitals monitor readmission rates to find out to what extent patients are readmitted for hospital-acquired conditions.

The Joint Commission's compendium contains strategies for hospitals to address the most common and deadly infections and germs.

P.J. Brennan, M.D. was involved in the creation of the compendium.

"Many of these infections occur every day all year long and many result in the death of patients. It's important to prioritize and put

them at the top of the list, so that hospitals and providers know what they should do," said Brennan, who is chair of the Health Care Infection Control Practices Advisory Committee (HICPAC), the federal advisory committee that provides guidance to the CDC and HHS on health care-associated infections.

But McCaughy contended that the recommendations in the Joint Commission's compendium on preventing infections "set the bar too low."

"Hospitals need to do more than what's in the compendium. I'm quite confident that it is not rigorous enough, because the standard of care is becoming higher than that," she said.

She suggests that hospitals take stronger measures, such as enforcing hand hygiene by penalizing those who violate hand-washing rules and screening incoming patients for MRSA.

"About 30 percent of hospitals now screen for MRSA. That will be the standard of care soon because it enables hospitals to isolate patients carrying the germ and prevent it from spreading to other patients through bedrails and other sites," she said.

McCaughy also advised that a "fool proof" method for avoiding central line-associated blood stream infections is to use a back-up catheter treated with antibiotic that kills the bacteria once it invades the catheter.

"Hospitals that fail to use these backup devices are inviting lawsuits, and surgeons who don't ask hospitals to have these devices will be vulnerable," she said. **MMLR**

Questions or comments should be directed to the writer at: sylvia.hsieh@lawyersusaonline.com



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From Beacon Hill

State imposes ban on temporary ER closures

The state has ordered hospitals to stop turning away ambulances when their emergency rooms are overcrowded.

The practice is decades old, but it can delay treatment and has upset patients when they can't get care at their usual hospital.

Paul Dreyer of the Department of Public Health said the temporary ER closures, called "diversions," don't solve the underlying problem of a lack of open beds in hospitals.

He told The Boston Globe that the practice causes other problems, such as shifting crowding to other hospitals.

Massachusetts General and Brigham and Women's hospitals in Boston have the state's highest diversion rates.

Dr. Alasdair Conn at MGH said that the diversion ban will be a big challenge for hospitals.

He said MGH is focusing on ways to discharge patients earlier to prepare for when the ban takes effect in January.

Hospitals' expansion into suburbs is checked

New measures adopted unanimously by the Public Health Council could substantially constrain Boston teaching hospitals from colonizing the suburbs, territory viewed by the city hospitals as prime terrain for growth.

Under the rules, companies that want to open outpatient clinics costing more than \$25 million will have to prove to state officials that their services will not duplicate existing services and will not imperil existing facilities.

Physician-owned outpatient surgery centers will undergo the same review, regardless of cost.

For at least two decades, outpatient facilities have been exempt from the scrutiny applied to hospital expansions.

But as Boston's resource-laden teaching hospitals opened satellite centers in the suburbs, community hospitals reacted with alarm, fearing for their survival. The new regulations are designed, in part, to address those concerns.

Spared \$64M hit, BMC still fears cutbacks

Boston Medical Center breathed a sigh of relief when the state Legislature protected a \$64 million special state payment, which Gov. Deval L. Patrick had sought to cut as part of his effort to close a \$1.4 billion budget gap.

But a BMC official said that hospital executives were concerned that Massachusetts will not honor its funding commitments this fiscal year, and they are already exploring cuts in patient services.

BMC and Cambridge Health Alliance, two so-called safety net hospitals, receive special "Section 122" payments from the state because they provide a disproportionate share of care to low-income and minority residents.

"We have been informed that the Commonwealth does not intend to honor its \$84 million Section 122 commitment to BMC for fiscal year 2009," said Tom Traylor, vice president of federal and state programs for BMC, in a statement e-mailed by a spokesperson.

Asked about the matter, a spokesperson for the Patrick administration's health and human services secretariat said the administration would "fulfill our obligations" to provide "\$287 million to Boston Medical Center and Cambridge Health Alliance in FY 09."

Gov. makes big cuts in health funding

Gov. Deval L. Patrick, who has emphasized the importance of health care cost control as a way to help state government minimize the impact of its fiscal crisis, cut funding for the state's new Health Care Quality and Cost Council by 37 percent, for a total cut of \$706,000.

The council, established under the state's 2006 health care reform law and looked to by advocates of cost control and health care quality, has been working on a long-delayed website to monitor the quality and costs of care at Massachusetts hospitals.

The funds will be slashed from the council's operations budget, which now stands at \$1.2 million.

Council officials have strongly advocated for budget increases since it was formed.

The state also cut \$293 million from its Medicaid budget, including \$40 million from the Cambridge Health Alliance for care it already provided to low-income residents.

The alliance, which runs three hospitals and dozens of clinics, says that cut plus other state cuts could total an amount equal to the cost of 650 full-time employees – or 20 percent of its workforce.



From Capitol Hill

Court blocks limits on Medicare reimbursement

A federal court in Washington, D.C. has blocked the Bush administration's efforts to save money on Medicare by paying for only the least expensive treatments for particular conditions.

Congress sets Medicare payment rates and never intended to give officials broad discretion to alter them, the court said in an important test case.

Judge Henry H. Kennedy Jr. said that the policy of paying for only "the least costly alternative" was not permitted under the Medicare law.

The administration's position would give the Secretary of the Department of Health and Human Services "enormous discretion" in determining the amount paid for each item and service covered by Medicare, without reference to the detailed formulas set by Congress, Kennedy said. "This flies in the face of

the detailed statutory provisions," he added.

The Bush administration argued that Medicare officials had the right to decide whether the expense incurred for a given item, not just the item itself, was "reasonable and necessary."

Kennedy pushes for universal health care

Sen. Edward Kennedy, D-Mass., reaffirmed his intentions to introduce universal health care legislation next year, the New York Times reports.

Kennedy, chair of the Senate Health, Education, Labor and Pensions Committee, directed staffers months ago to begin work on a health care bill that would significantly expand coverage. He said that he will "continue to lay the groundwork for early action by Congress on health reform when President Obama takes office in January."


"We've been making real progress in our discussions about a consensus approach and I'm optimistic we'll succeed," he added.

Kennedy indicated that he believed Obama would sign a health care bill early in his presidency, according to the Boston Globe.

Congress faults FDA on foreign drug oversight

The Food and Drug Administration is failing to keep accurate data about foreign drug facilities it is supposed to oversee and often


Continued on page 15

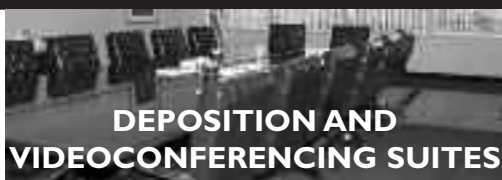


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Doctors must prepare now for new identity theft rules

Continued from page 1

employment purposes, have been required to comply with new rules for responding to an address change or discrepancy.

Overlap with HIPAA

The rules, which require implementation of policies to find and respond to "red flags" of identity theft, can be found on the FTC's website at www.ftc.gov.

The rules have substantial overlap with security rules under the Health Insurance Portability and Accountability Act (HIPAA) that most providers have already implemented to address improper access to patient information.

This should help reduce the burden on providers, said Eller.

"As a result, the red flag rules represent an opportunity to go back to some of these policies and procedures and ask, 'Are these measures we're taking doing enough to secure information against identity theft in ad-

dition to just improper access?'" said Veronica Marsich, a shareholder at Smith Haughey Rice & Roegge in Ann Arbor, Mich.

Some examples of "red flags" include suspicious information supplied by a patient, such as inconsistent Social Security numbers or other mismatched personal information.

The policy must include "appropriate responses" to prevent and mitigate identity theft once a red flag is found, such as a clear chain of communication for notifying a risk manager or other compliance officer.

The regulations also require that the policy be approved by the entity's board of directors and updated every year.

Another requirement is that covered entities train employees on the written policies.

"This is not a trivial process," said Eller. "In addition to setting up a written program, another element is training staff so they know what to do when a red flag pops up."

The regulations provide for civil penalties, such as monetary sanctions and enforcement action by the FTC.

New standard of care?

Some lawyers predict that the new rules will become the standard of care in litigation involving identity theft.

"As the red flag rules become more prevalent and companies adopt them, that will become the standard for what a reasonable company does," said Jack Gravelle, an attorney with Porter Wright in Columbus, Ohio.

"If identity theft occurs, a plaintiff's attorney may well use the lack of a red flag program against the provider, contending that the provider was negligent in failing to implement the safeguards such a program would have provided," said Eller.

Eller noted that additional guidance is expected from the FTC in the next several weeks that lawyers hope will further clarify the rules.

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Questions or comments should be directed to the writer at: sylvia.hsieh@lawyersusaonline.com



HELPFUL RESOURCES:

Providers can start to look for sample policies, seminars and other support from professional associations.

- The World Privacy Forum has published suggestions for health care providers on the red flag rules and the earlier address discrepancy requirements, which you can find at www.worldprivacyforum.org.
- The American Health Lawyers Association sells a LexisNexis product containing analysis and tools on red flag compliance, geared toward health care attorneys. Their website is www.healthlawyers.org.



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Bibliography – see page 14

New e-prescribing regulations applauded by doctors, lawyers

By Eric Berkman

As part of the federal government's ongoing push to make health care go paperless, the Centers for Medicare & Medicaid Services (CMS) recently adopted final standards for electronic prescribing under Part D, Medicare's prescription drug benefit.

Under the new regs, which take effect April 1, 2009, any physician who electronically prescribes drugs covered under a Part D plan must comply with new CMS standards for:

- Communication of formulary and benefits information between providers and Part D plan sponsors;
- Communication between providers about a patient's medication history; and
- Pharmacy-to-provider fill-status notifications.

The new regs also require physicians who are using e-prescribing to identify themselves using the National Provider Identifier (NPI).

While e-prescribing remains optional for physicians and pharmacies, Part D plans will be required to have the proper infrastructure in place to support e-prescribing.

And any Part D plan that offers e-prescribing will be required to adhere to the new standards.

Physicians and health care attorneys laud these new standards as a positive development given the advantages of e-prescribing from a risk management and operational standpoint.

But they also say the standards don't go far enough to achieve the government's goal of universal e-prescribing under Medicare by 2011. Legislation that is currently pending in Congress would penalize physicians who are not prescribing electronically by that time.

For example, standards for critical pieces such as structured and codified SIG (which would create standardized ways of writing directions for using medication), clinical drug terminology and prior authorization of certain drugs remain incomplete.

Meanwhile, the new standards don't clear some of the government's own roadblocks to complete implementation, such as its ban on e-prescribing of controlled substances.

"It's a step in the right direction, but it's not big enough," says Steven J. Stack, head of the emer-

gency department at St. Joseph's Hospital East in Lexington, Ky., and chair of the American Medical Association's Health Information Technology Advisory Group. "Far and away, physicians will embrace e-prescribing as a means to improve patient safety, improve efficiency and improve quality of care, but the government has to finish its homework first so the system will really work."

Meanwhile, observers point to cost concerns and the lack of systems directly approved by CMS as additional barriers to widespread implementation.

"It would be nice if CMS would actually certify certain vendors as meeting their standards," says Shrewsbury gynecologist Dale Magee, past president of the Massachusetts Medical Society. "Doctors don't buy computers and software that often and I would hate to see doctors being confused by vendors who overpromise what their product can deliver."

The standards

The government's push for e-prescribing began in 2003 with the Medicare Modernization Act, which gave birth to Part D, the vol-

Continued on page 14

The legal pros and cons of e-prescribing

Though some physicians contend that the new standards for electronic prescribing from the Centers for Medicare & Medicaid Services (CMS) aren't sufficiently comprehensive to spur an immediate groundswell of e-prescribing adoption, attorneys agree that implementation can carry substantial legal benefits.

The biggest benefit is the reduction of errors, particularly from a legibility standpoint, says Boston lawyer Colin Zick.

"First and foremost, you eliminate the handwriting issue," says Zick, who practices with Foley Hoag. "If you're presented with choices of drugs [on a screen] and you tap on a particular one, you've sent the right choice."

Additionally, many systems have intelligent features that check the prescription against whatever else is in the patient's electronic medical record and prompt the physician to double-check in the event of a suspected input error, Zick says.

"It can do the same thing with dosages. There are all sorts of ways to apply the technology with an aim to reduce error," he adds.

In addition to handwriting errors, e-prescribing can eliminate transcription errors that may occur at the pharmacy when receiving phoned-in prescriptions, says Linn Foster Freedman, a health care lawyer and partner at Nixon Peabody in Providence, R.I.

"My husband is a physician and I hear him calling into pharmacies all the time, especially on the weekend when a patient calls in need of a prescription," she says. "A lot of times he's leaving a prescription on a voice recorder or answering machine. The risk associated with voice messaging of different medications is significantly reduced

with e-prescribing."

E-prescribing can also reduce risks created by similar-sounding drug names, says Boston attorney David Szabo, a partner at Nutter, McClennen & Fish.

He explains that with so many new medications coming out, drug companies and pharmacies are running out of names.

"Some sound very similar even when they're very different – either different-acting or for a different purpose," he says. "Paired with the legibility issue, this creates a risk of mix-ups or transcription errors on a piece of paper a patient is handing to the pharmacist."

But to glean the full risk-management benefit, lawyers agree that the transaction must be paperless at both ends. This means doctors should think twice about systems that transmit prescriptions to a pharmacy by fax.

E-prescribing by fax is not only noncompliant with the new CMS standards, but it creates a risk of transcription errors at the receiving end, Szabo says.

"They can print the thing out on a fax machine, but someone has to type it in again on a keyboard or write it on a piece of paper," he says.

Drug interactions are the other big safety issue addressed by e-prescribing, says Zick. If all the entities involved in the transaction are in contact about the medications a patient has been taking or is currently taking – as e-prescribing allows for – it can reduce the potential for adverse events, he says.

However, e-prescribing also presents significant traps for the unwary. As with any kind of electronic transaction, information security and patient privacy are the two biggest potential trouble spots, attorneys say.

Accordingly, Freedman urges providers to be aware of relevant security and privacy provisions in both HIPAA and Massachusetts state law.

"You want to be able to prevent breach, hacking and inadvertent disclosure of that information," she says. "More than that, if a physician is prescribing things like Prozac or methadone, there are additional safeguards that must be taken to ensure that there's no breach or disclosure of such sensitive information."

Zick adds that doctors who do their e-prescribing using handheld devices need to be particularly careful.

"In the trade press, not a day goes by where you don't see that some provider has lost a laptop or other device with someone's health information on it," he says. "If you're working off a handheld and it has everyone's prescription information and it's not password protected, then it's just like losing a cell phone or a BlackBerry. But instead of phone numbers or e-mails, you have 100, 1000 or 2000 prescription records."

This means providers need to install the right kind of security on these devices or they could wind up with issues under both federal and state privacy law, Zick says.

Finally, Szabo urges providers to maintain good backup systems in case of outages or waterpipe leaks.

"Have your records backed up every day so you can always restore your records of prescribing activity so you can produce them later on in case of an audit," he says.

MMLR
— Eric Berkman

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New e-prescribing regulations applauded by doctors, lawyers

Continued from page 13

untary Medicare prescription drug benefit. It also included provisions to foster e-prescribing by requiring certain standards and allowing third parties, such as hospitals, to offset the costs.

By the beginning of 2006, CMS had standards in place covering transactions for new prescriptions as well as requests for prescription refills, changes and cancellations. CMS also adopted standards for eligibility and benefits queries.

In November 2007, CMS published the results of pilot tests for five new standards: formulary and benefit information, medication history, prescription fill-status notification, structured and codified SIG and prior authorization.

CMS was satisfied with the standards for the first three tools but not the latter two. Accordingly, on April 2, 2008, it adopted those three standards only—in addition to mandating that providers use their NPI when prescribing electronically.

Here is a look at the benefits of

e-prescribing systems that include the types of information covered by the new standards:

• Formulary and benefit information

An e-prescribing system that provides instant access to formulary and benefit information—such as informing a doctor that a particular drug isn't covered or that a generic or off-patent drug will carry a lower co-pay—enables physicians to address coverage issues with the patient up front, says Boston health care attorney David Szabo, a partner at Nutter, McClennen & Fish LLP.

A doctor “can avoid the whole paper chase where a patient gets a prescription, goes to the pharmacy, is told it's \$50 a pill, gets upset, and calls you, forcing you to call the health plan or change the prescription,” he says. “Some systems may actually be able to provide a doctor with backup clinical information about alternative medications or a mechanism for the doctor to appeal for coverage of a higher-cost drug.”

Eric Poon, an internist at Brigham and Women's Hospital in Boston, agreed. “Having formulary support is often very helpful,” says Poon, who is also the hospital's director of clinical informatics.

However, he wonders if there's enough technological integration at this point to make these systems work.

“It's not clear how this will be implemented across all different Medicare Part D plans to make sure there's good mapping between the e-prescribing system the physician will be using and what's actually on the formulary,” Poon said. “The system needs to be able to recognize what the insurance company will pay for.”

• Medication history

The medication history standard is equally critical because the e-prescribing system will put doctors on notice of potentially bad drug interactions, says Szabo.

“You have a system that can show the doctor what drugs the patient has purchased in, say, the last six months,” he says. “Even if there's no

drug-drug interaction, the doctor might look at the list and say, ‘Boy, you're taking a lot of pills here.’”

It's also useful for medication reconciliation in cases where elderly, incompetent or other patients can't clearly tell the doctor what medications they're on, Szabo adds.

But on the flip side, Poon warns that this can potentially be too much of a good thing.

“It's very easy for a system to over-alert,” he says. “Physicians may get too many alerts as they try to prescribe and may blow past all of them. They could throw the baby out with the bathwater and miss the one truly important interaction.”

• Fill-status notifications

Meanwhile, fill-status notifications can be a valuable tool to help physicians follow up on their patients, says Boston lawyer Colin Zick, who practices with Foley Hoag LLP.

“Let's say you prescribe medicine for high blood pressure and they stop taking it, because they don't like it, it costs too much and

they're taking half as much as they're supposed to, or they share it with their spouse,” he says. “Now you have this compliance issue. Fill-status notification doesn't tell you how to solve that problem, but at least you know an issue is there and you can try to address it.”

But Zick wonders whether this tool can create a legal obligation for the doctor to follow up. “And if you undertake the follow-up, do you have the additional duty to keep following up? I don't know the answer, because this is brand new.”

David Harlow, an attorney and health care consultant in Newton, says he doesn't know the answer either.

“But I'm sure a plaintiff's attorney would certainly bring it to a patient's attention,” he says. “As with any tool, if it's available and you don't use it, it'll be held against you one way or another.” **MMLR**

Questions or comments should be directed to the editor at: reni.gertner@mamedicallaw.com

The Physician's Corner: E-prescribing: Its time is here

By Henry Tulgan, M.D., FACP

The CMS National E-Prescribing Conference and a number of other regional and local educational activities are helping make physicians and other prescribers aware of the value of e-prescribing.

An important impetus for e-prescribing, in part, is the Medicare Modernization Act of 2003, which created Medicare Part D, the voluntary Medicare prescription benefit.

As early as 2006, CMS created a number of proposed standards to be tested in a pilot program. In 2007, CMS chose three locations for the program, which will be extended and required on April 1, 2009 for Part D plans.

As of December 2008, though, when this CME activity was published, e-prescribing remains optional for physicians and pharmacies.

The federal government hopes to make e-prescribing a requirement by 2011 or 2012. And recently, Blue Cross Blue Shield of Massachusetts announced that by 2011 it will require physicians to use e-prescribing in order to qualify for bonus payments.

The following are the three CMS-mandated e-prescribing standards:

• Formulary and benefits information sharing between providers and Part D plan sponsors.

The purpose is to alert prescribers instantly if a drug is not covered or if a similar one or a generic may be substituted.

• Medication history communication between providers.

The advantage is to avoid potentially harmful drug interactions, polypharmacy—where a patient is taking too many drugs—and lack of compliance.

• Pharmacy to provider fill-status notification.

This is another way to check for compliance.

One additional need is for prescribers to use their National Provider Identifier (NPI). For those who have not already obtained an NPI, it can be obtained from <https://nppes.cms.hhs.gov>. Although applicants are told that this is a 20-minute process, in reality it can be completed much more quickly. In

most instances the NPI will be issued by return e-mail.

Although the start of required e-prescribing under Medicare is near, a number of issues persist.

First, the absence of a standard and codified SIG (medication instruction) means there may still be prescribing errors due to the use of abbreviations and shorthand. Also, CMS has not yet adopted standards for drug terminology and prior authorization. To date there is still a ban on using e-prescribing for controlled substances, which instead must be written on special tamper-proof paper.

Additionally, there are IT considerations for prescribers. The implementation of stand-alone and EMR-based e-prescribing systems varies in cost and features. Small practices may lack the resources to fully evaluate them. It helps that there are several systems that have been tested as part of SureScriptsRxHub's vetting process. All vendors who are listed on the SureScripts website (<http://www.surescripts.com/get-connected.aspx?ptype=physician>) meet the 2009 Part D standards for the functions they provide.

Fortunately, there are safe harbors for technology grants, and BCBS has suggested that it will make it easier to implement e-prescribing systems. Whatever system is chosen, the Health Insurance Portability and Accountability Act (HIPAA) and state law must be obeyed. In order to manage risk, the system must be secure—limiting who has access to it—and it must be backed up daily.

It's important to note that attorneys have scrutinized e-prescribing carefully. While they recognize its potential advantages, some wonder if the notification of fill status requirement could create a legal obligation for the physician to follow up with the patient. As a result, additional e-prescribing standards may be added in the future.

Risk management strategies

- The transaction must be paperless at both ends to reap the full risk-management benefit,
- Make sure your e-prescribing system is password-protected, especially if you are using a handheld for e-prescribing.
- Check for and use your e-prescribing system for intelligent features that check for drug interactions and drug allergies.

scribing system for intelligent features that check for drug interactions and drug allergies.

• Be aware of relevant security and privacy provisions in both HIPAA and Massachusetts state law.

Henry Tulgan, M.D., FACP is a clinical professor of medicine at the University of Massachusetts Medical School, a consultant to the MMS Committee on Sponsored Programs, which he formerly chaired, and Director of Medical Education at Wing Memorial Hospital in Palmer, Mass.

Bibliography

HIMSS “How To” Implement the Medicare E-Prescribing Incentive Program
<http://www.himss.org/content/files/ePrescribingQuickTips/HIMSSe-prescribingTip-SheetMedicareIncentive.pdf> (PDF - 31 KB)

A Clinician's Guide to Electronic Prescribing
http://www.ehealthinitiative.org/assets/Documents/e-Prescribing_Clinicians_Guide_Final.pdf (PDF - 553 KB)

Massachusetts Medical Law Report
“Holding on to your prescription pad? Barriers to e-prescribing”
Summer 2008
<http://mamedicallaw.com/blog/2008/06/11/holding-on-to-your-prescription-pad-barriers-to-e-prescribing/>

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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 December 16, 2009. Please make a copy for your records.

1. E-prescribing standards will include all of the following except:
 - a. Formulary and benefits information
 - b. Medication history
 - c. Fill status notification
 - d. SIG regulations
2. To e-prescribe it is required to have a National Provider Identifier (NPI).
 - a. True
 - b. False
3. It will be permissible to prescribe controlled substances when the federal program commences.
 - a. True
 - b. False
4. Safe harbor legislation may allow practices to receive technology donations.
 - a. True
 - b. False

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What are your topics of interest for future CME activities?

'Through a glass, Starkly': CMS changes the Stark Law

Continued from page 3

cians, thereby meeting a Stark direct relationship exception.

Space and equipment leases

Up until this year, CMS has permitted percentage-based compensation formulas and per-click rental payments under the Stark exceptions for space and equipment leases.

CMS has reversed its position on these arrangements in the 2009 IPPS final rule.

As of Oct. 1, 2009, the office space and equipment lease exceptions will prohibit the use of percentage-based compensation and unit of service or "per-click" payments.

The fair market value and indirect compensation arrangements exceptions will also limit per-click payments.

Percentage-based compensation arrangements can still be used in non-leasing rela-

tionships, such as management and billing contracts. CMS, however, will continue to monitor these arrangements and may make modifications in future rules.

The "per-click" payment prohibitions apply whether the referring physician is the lessor or lessee.

CMS also stated that time-based rental agreements, if structured properly, may meet the requirements of the office space and equipment lease exceptions. However, on-demand leases for small blocks of time (e.g., once a week for four hours) are problematic.

In-office ancillary services

Under the 2008 PFS, CMS expressed its concern about the shared use of space or equipment for the provision of lab or radiology tests, such as block lease, per-use fee and other shared facility arrangements, and

suggested it may adopt specific restrictions in the future.

Anti-markup provisions

The 2008 PFS changed the rules on marking up the cost of diagnostic tests.

Under the revised rules, physicians or group practices may bill Medicare for the technical or professional component of diagnostic tests performed by a supplier outside of the physician or group practice's clinical site. However, the charge is limited to the lower of: (1) the net amount charged to the physician/group practice, (ii) the billing physician/supplier's actual charge; or (iii) the test fee schedule amount, if the performing supplier billed directly.

Strong reactions from the physician community convinced CMS to delay the effective date of the anti-markup provisions until Jan. 1, 2009. CMS has promised that it will

issue clarifying guidance on the anti-markup rule.

Conclusion

You can expect CMS to continue to make refinements to the Stark Law, so the ongoing efforts to make sense of it will continue to be a challenge.

But getting it right is not optional.

Non-compliance can result in denial of payment, refunds, civil monetary penalties up to \$15,000 per claim, an assessment of up to triple the amount claimed for each service that was the basis for a penalty, and program exclusion.

Violations can also serve as a basis for a whistleblower lawsuit under the federal False Claims Act.

Physicians, medical practices, hospitals and other health care providers have too much at stake to treat Stark as an unsolved mystery.

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Bills, Rules & Regs

Continued from page 11

doesn't follow up warning letters with inspections, according to a report by the investigative arm of Congress.

The Government Accountability Office report came amid congressional pressure for tighter oversight of foreign drug plants that supply many of the pills Americans take, according to the Wall Street Journal.

From fiscal 2002 through 2007, the FDA issued 15 warning letters to foreign companies with serious deficiencies, such as product impurities and record-keeping problems.

The agency only re-inspected four of the companies, and then only two to five years later, the report says.

The GAO also said that the FDA often relies on information provided by the companies in deciding whether they have fixed problems. In the report, the FDA said that it agrees there should be more inspections, but money should be spent elsewhere as well.

The House Energy and Commerce Committee introduced a bill that would mandate foreign inspections at a rate close to that of FDA inspections of U.S. plants. U.S. compa-

nies are inspected about every 2.7 years, but the rate for foreign inspections is roughly once every 13 years, the Journal reported.

Drug maker's gifts to psychiatrists probed

A Senate committee that is probing payments to doctors by drug and medical device makers has asked Johnson & Johnson about support of psychiatric professional groups.

J&J, of New Brunswick, N.J., is responding to a request from the Senate Committee on Finance, the company said in a regulatory filing. The letter asks about "any payments or benefits to a number of specified psychiatrists associated with psychiatric professional associations or otherwise authorities in their field."

The new inquiry "would be part of [Iowa Sen. Charles] Grassley's work to determine more about the accuracy of disclosures of financial relationships between industry and doctors," said Jill Kozeny, a spokesperson for the senator, in an e-mail.



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- Chronic Myelomonocytic Leukemia (CMML)

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Other Inherited Disorders

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Other Malignancies

- Breast Cancer
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