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Protecting your patients' data

By Meghan S. Laska

The federal mandate requiring that all medical records be converted to an electronic format by 2015 has heightened concerns about protecting the confidentiality of patient data. Even an unintentional security breach can land doctors in serious legal trouble, whether they are storing data or sharing it with third parties.

Complicating the issue is the emergence of health information exchanges, which tend to vary from community to community in terms of their structure and security measures. Some simply relay data within a network, while others transmit and store patient information. Either way, it's unlikely that an exchange will be 100 percent protected against hackers, so it's important for physician practices to weigh the risks and benefits of participation.

"There are pro-privacy people on one side who believe that the risk of any disclosure of patient information is so horrific it must be prevented at any cost and others who say the need to exchange information is so great that there must be some tolerance of the risk of exposing patient privacy," says Craig Schneider, director of healthcare policy at the Massachusetts Health Data Consortium in Waltham.

The key, he notes, is finding a balance between those sides.

So how do physicians find the right balance and manage risk when it comes to protecting patients' electronic health information? Experts say that there are some "rules of the road" that can help doctors navigate this changing landscape and avoid pitfalls.

Learn the law

Familiarizing yourself with the applicable federal and state laws is a good place to start when considering patient privacy issues. While doctors presumably know about additional consent requirements that cover specific types of

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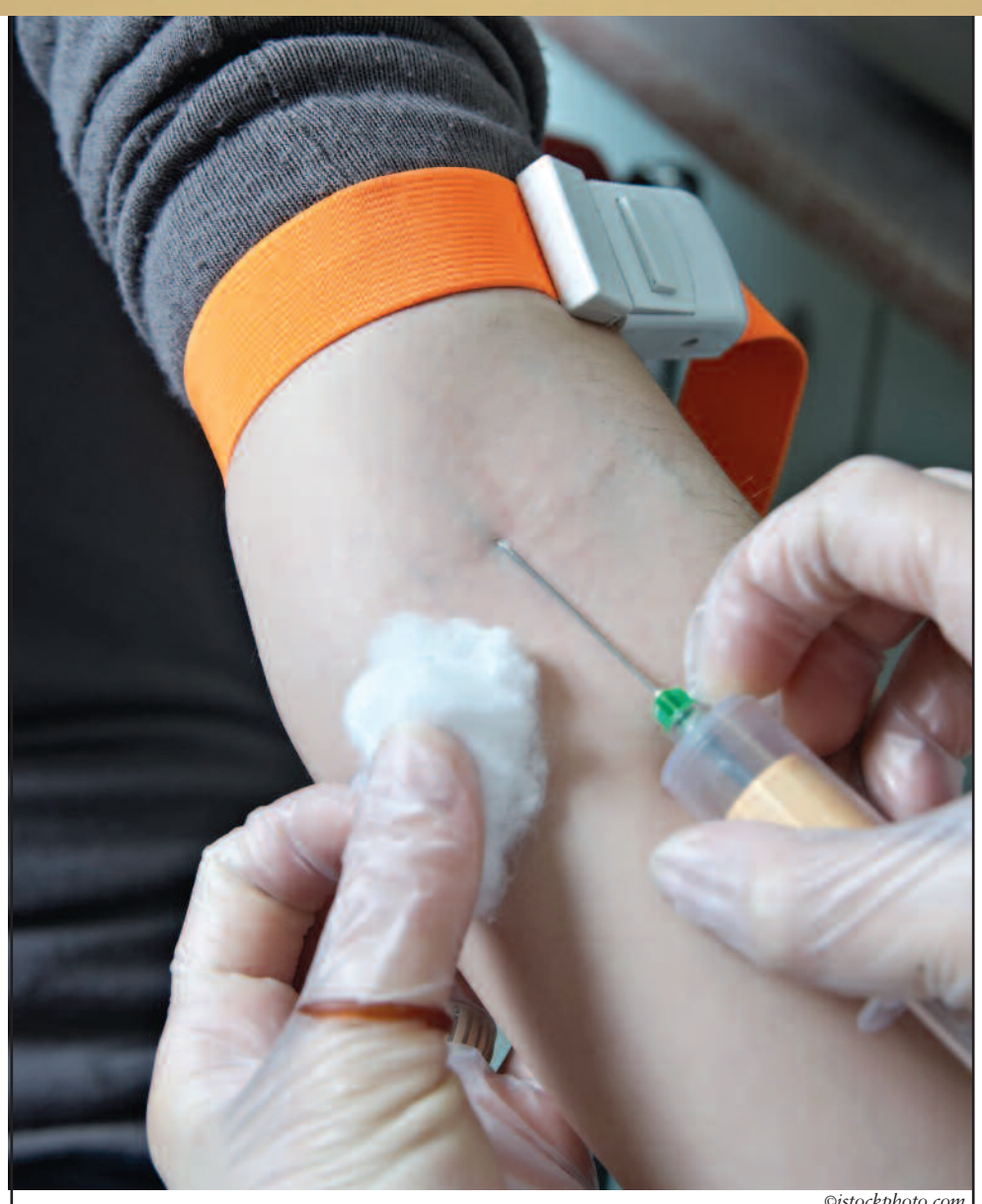

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State HIV bill would require doctors to offer screening to patients

By Jane Pribek

Controversial legislation pending before Massachusetts lawmakers would make offers of HIV screening a routine part of primary care, but physicians are debating whether the measure would work well in practice.

The legislation would require every provider of primary care or infectious disease services, including obstetricians and gynecologists, to offer HIV tests to their patients.

One version of the measure, H. 2906 and S. 1108, which was debated at a hearing in April, is sponsored by Sen. Patricia Jehlen, D-Somerville, and Rep. Bryon Rushing, D-Roxbury. A new version of the bill introduced in July, H. 3594, essentially incorporates the language of the first one with an additional provision regarding release of records to third parties. That measure is sponsored by Rep. Jeffrey Sanchez, D-Jamaica Plain.

Everyone agrees on the legislation's overarching goal: to curb the spread of HIV/AIDS. But the devil is in the details.

Some members of the state's medical community, including the Massachusetts Medical Society, oppose provisions of the bills that would require a patient's verbal informed consent for conducting an HIV test to be documented in his or her medical record. They say this requirement is cumbersome and that electronic medical records systems might not be able to accommodate it.

They also argue that another provision that would require written consent to release information related to the test to third parties in some cases is burdensome for physicians and could hinder their provision of high quality care.

Their position is in conflict with some members of the state's gay and lesbian community, who insist that rigorous pri-

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HIPAA audits set to begin

By Correy E. Stephenson

The Department of Health and Human Services has contracted with two different parties to conduct audits of entities covered by the 1996 Health Insurance Portability and Accountability Act.

What that means for covered entities "is that the audit program is coming," cautioned Adam H. Greene, a partner in the Washington, D.C. office of Davis Wright Tremaine who formerly worked at HHS' Office for Civil Rights and focuses his practice on HIPAA compliance.

Under the auspices of the 2009 HITECH (Health Information Technology for Economic and Clinical Health) Act, HHS was mandated to conduct audits of covered entities to ensure compliance with data security and privacy requirements.

Prior to HITECH, HHS investigated potential HIPAA violations based on specific complaints. But HITECH imposed a requirement to conduct periodic audits to ensure that covered entities and business associates are complying with the HIPAA rules.

"Covered entities" include health care providers, health plans (including insurance companies and HMOs) and health care clearinghouses, such as billing services for physicians. "Business associates" are entities that perform functions on behalf of covered entities that involve disclosure of protected health information, such as medical data contractors or law firms that represent health care providers.

In June, the department awarded two contracts related to the audit requirements. The first went to Booz Allen Hamilton, for $180,000 for "audit candidate identification."

The department then awarded a $9.2 million contract to KPMG to create an audit protocol and conduct up to 150 audits of covered entities by Dec. 31, 2012.

According to the contract synopsis, each audit will include a site visit with interviews with various leadership officials (such as the chief information officer, legal counsel and director of medical records) and an examination of the physical features, operations and adherence to policy.

In addition to data from the site visit, reports would include a timeline and methodology of the audit as well as specific recommendations the entity can take to address identified compliance problems, complete with a corrective action plan.

Recommendations for HHS regarding oversight and the need for any corrective action will also be included.

With audits set to begin late this year

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Stepping back to realize how lucky we are

One Saturday in July I was talking to a friend about how lucky I felt that I had only had to take my son to the emergency room once in his life.

As I uttered those words, a small, superstitious part of me was thinking I shouldn't have, and then I moved on with my weekend.

The next evening, I found myself in the ER at Children's Hospital Boston with a four-year-old boy who had fallen face first onto a cement floor in the bathroom at the swimming pool.

I was standing with Brett when he fell, and I was the one who lifted him up and caught the first glimpse of his swollen, bleeding chin, lip and mouth.

In moments of crisis, I'm unusually calm. It's not that I'm not panicked on the inside. It's more that it's mind over matter for me. I would never let my child see my fear, the part of me that couldn't stop worrying about how his fall could have been so much worse.

As soon as he said, "Mommy, my top teeth are loose," I knew our next stop was Children's Hospital. And while I was suddenly thrust into my second visit to the ER with Brett, the whole experience continued to remind me how lucky we are.

Editor's Note

We encountered nurses, physicians, physician assistants and countless others who were attentive and focused on Brett's care and well-being. We had two dental consults on a Sunday night, something that isn't even available in many children's hospitals across the country. His follow-up care has been equally stellar.

I'm also lucky to have a child who is incredibly brave. You may recall he is fascinated, not traumatized, by such things as flu shots and having his blood drawn.

In his usual form, he didn't cry once after we entered Children's. As his face continued to swell and doctor after nurse after dentist checked his torn frenulum and wiggly teeth, he was cracking jokes. And he was especially pleased to obtain his own mini-DVD player showing 101 Dalmatians.

We went home that night with a child who was a little sad and uncomfortable, but who was going to be absolutely fine. I breathed a sigh of relief. It wasn't until 48 hours later, after I put a child to bed who was improving as the minutes rolled by, that I sat on the couch and burst into tears.

Writing about medicine all day, or working in medicine all day, it's easy to forget how lucky we are to have our health, and to have an excellent and caring health care system there when we don't – things most of the world can't take for granted. It's important sometimes to step back and reflect on our good fortune, the hard work that keeps it going and how much more work is needed to make the less fortunate feel so lucky.

— Reni Gertner, MPH

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www.mamedicallaw.com
For editorial inquiries, e-mail reni.gertner@mamedicallaw.com or call 800-444-5297, Ext. 12142.
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Avoiding exclusion from federal health care programs

By Christopher J. Hunter

Exclusion from participation in federal health care programs can be professionally devastating and financially ruinous for individuals and entities.

Health care providers and entities that are excluded from Medicare, for example, are deprived of significant revenue and suffer potentially fatal damage to their reputation. The bases for mandatory exclusion have generally been clear and avoidable.

But less clear, and potentially less avoidable, have been the bases for permissive exclusion, or, in other words, exclusion that is not required by statute.

What's more, the risk of permissive exclusion appears to be rising. Recent federal government guidance, enforcement activity and legislative proposals all indicate an ever-broadening interpretation of when permissive exclusion authority will be exercised.

Severe penalties

The U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) exercises mandatory and permissive exclusion authority as one of several methods of protecting the integrity of federal health care programs.

An excluded individual or entity is prohibited from billing the government for services or items provided to patients. Entities that employ an excluded individual may not bill the government for services or items he or she provides. Similarly, entities may not submit reimbursement claims based on services or items provided by an excluded third party vendor or supplier.

The penalties for violating these rules are severe. An entity that bills for services rendered by an excluded provider may face civil monetary penalties of $10,000 per occurrence, triple damages for the amount claimed for each item or service and exclusion from participation in federal health care programs.

Mandatory exclusion occurs upon conviction for certain categories of criminal offenses and is for a minimum of five years. Felony convictions for health care fraud, crimes relating to patient abuse or neglect and controlled substances offenses trigger mandatory exclusion. Mandatory exclusion is easy to avoid: comply with the law and the risk of mandatory exclusion never presents itself.

The bases for permissive exclusion are many and, to a degree, more subjective. For example, convictions for crimes such as obstruction or fraud unrelated to health care programs may result in exclusion. Other trigger events include license revocation or suspension, submitting claims for medically unnecessary services or failing to supply information about subcontractors and suppliers. The duration of exclusion depends on the basis for exclusion.

One basis for permissive exclusion that has recently been the subject of significant attention relates to individuals controlling a sanctioned entity. Federal law authorizes HHS-OIG to exclude, among others, officers or managing employees of an entity that has been excluded or convicted of certain crimes.

HHS-OIG guidance

This basis for exclusion is the most frightening because the officers or managing employees can be excluded even if they had no knowledge of the wrongful conduct that resulted in their employer being sanctioned.

In October 2010, HHS-OIG issued a guidance document identifying the factors it will consider in deciding whether to impose permissive exclusion on unwitting officers and managing employees.

HHS-OIG identified four factors to guide its analysis. First, what were the circumstances of the misconduct and seriousness of the offense? To answer this question, HHS-OIG will examine the conduct itself. Did the misconduct result in actual or potential harm or cause financial harm to federal health care programs? Was the misconduct an isolated incident by one field-level employee or does it reflect officer-level involvement?

Second, what was the officer's or managing employee's role in the sanctioned entity? To answer this question, HHS-OIG will look to the individual's current and former positions with the entity and the degree of managerial control or authority. On this point, HHS-OIG asks: Did the misconduct occur within the individual's chain of command?

Third, what were the officer's or managing employee's actions in response to the misconduct? Did the individual immediately try to stop the misconduct, mitigate its effects and disclose it to the government? Did the individual cooperate with government investigators and prosecutors by providing them with documents and other evidence upon request?

Fourth, what is the nature of the entity itself? Is the entity a first-time offender or is the misconduct part of a recurring pattern? Is the entity large and complex, with a mature corporate governance structure, or is it small, with a limited number of employees trying to accomplish a lot with a little?

Enforcement

Two months after HHS-OIG issued this guidance, a federal judge upheld a 12-year permissive exclusion determination imposed on three former executives of Purdue Frederick Company, Inc. who had no actual knowledge of wrongdoing at their company.

The excluded executives were the company's former CEO, former Chief Medical Officer and former General Counsel.

The exclusion determination arose out of the misbranding of OxyContin. The company pleaded guilty in May 2007 to felony misbranding, and each of the three corporate officers pleaded guilty to misdemeanor misbranding.

In this case, the convictions were based on strict liability. That is, they were convicted even though there was no evidence they had actual knowledge of criminal wrongdoing. The government used the responsible corporate officer doctrine, also known as the *Park* doctrine, to hold them criminally accountable for failing to prevent, detect and correct the misbranding of OxyContin.

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Christopher J. Hunter is a former Assistant U.S. Attorney and FBI agent. He also has served as Counsel at LibbyHoopes, P.C., www.libbyhoopes.com, in Boston.

Listening In

The news beat of the medical profession

Patient visits to state health centers surge

Massachusetts community health centers saw a 31 percent increase in patients from 2005 to 2009 despite an increasing population of residents with health care coverage, a new report has found. The report concluded that the centers "remain a vital source of care even when people gain insurance."

The study was conducted by researchers at George Washington University and University of Minnesota and published in the Archives of Internal Medicine.

It found that the vast majority of patients sought health care services at community health centers and hospitals that care for a disproportionate share of low-income or uninsured residents by choice, not because they had difficulty obtaining care elsewhere.

"The presumption is [that] safety net providers are providers of last resort when you are desperate, but that is not what their patients perceive," GWU researcher Leighton Ku said. "They seem to like these places and do not feel the need to go elsewhere."

According to the study, 20 million Americans receive care at 8,000 community health centers, a figure that is expected to double by 2015.

Diabetes app helpful in managing disease

A randomized controlled trial in the U.S. of a mobile application's ability to improve health outcomes found that patients who used the app to help manage their diabetes had better outcomes than those using traditional means, according to American Medical News.

The mobile app studied in the trial was WellDoc's DiabetesManager, an FDA-cleared application that collects data, analyzes it and provides real-time patient coaching.

The application also allows physicians to create their own rules about what data are sent to them to help deliver personalized feedback and care plans.

The study, conducted by the University of Maryland School of Medicine and released online before its scheduled publication in the September issue of Diabetes Care, found a mean decline in A1C levels of 1.9 percent among those who used the mobile tool over a year, compared with 0.7 percent among those receiving traditional care.

ER docs decry lack of psychiatric beds

Mental health patients are treated unfairly compared to patients with other medical conditions, often left in emergency rooms for days waiting for beds in psychiatric units, or sent home without the care they need, ER physicians told the Joint Committee on Mental Health and Substance Abuse.

Doctors said ERs are too often "boarding" mental health patients because caregivers are unable to find a psychiatric hospital willing to accept them, and that physicians are forced to navigate several layers of bureaucracy with insurance companies and then with psychiatric units, trying to convince them individuals need in-patient care.

Insurance company executives argued there are not enough psychiatric beds available and asked the lawmakers to put a moratorium on closing any more state hospitals.

While DPH officials acknowledged a problem, they said they found the average wait time for a MassHealth recipient to see a behavioral health specialist is 47 minutes. Those who require hospitalization are placed within two hours.

But doctors like Dr. Gregory Volturo, emergency department chair at UMass Memorial Medical Center, said they see much longer wait times. On weekends, finding a bed for a psychiatric patient is "nearly impossible," Volturo said.

MassHealth sued for violating ADA

The Disability Policy Consortium has filed a lawsuit against MassHealth, contending that the Medicaid agency that insures more than 1 million Massachusetts residents has failed to provide disabled applicants with adequate communication options.

The suit, filed in U.S. District Court by the consortium and eight plaintiffs – including four blind residents, two deaf residents and two with other disabilities – argues that MassHealth violated the Americans with Disabilities Act by failing to provide Braille or electronic forms that can be filled out without assistance and failing to offer materials in American Sign Language.

The suit also claims that the agency generally makes it difficult to contact a live customer service representative.

Several plaintiffs who have been MassHealth members for decades say that their health care services were canceled or suspended as a result of their inability to fill out required paperwork and because of the agency's inability to offer assistance, despite requests for interpreters, accessible forms or other help.

The consortium is asking a judge to force MassHealth to ensure that its disabled clients receive all "forms, materials and other communications in an accessible format of their choice within a reasonable time," and to require that the agency permit callers to bypass its automated system for a live representative. The group is also seeking monetary damages for pain and suffering.

Suits over hospice care on the rise

As hospice care has evolved into a $14 billion business run mostly for profit, patients and their families have paid a steep price, according to lawsuits and federal investigations.

A report by Bloomberg indicates that providers have been accused of boosting their revenues with patients who aren't near death and not eligible for hospice – people healthy enough to live a long time with traditional medical care.

New federal hospice investigations rose 50 percent between 2008 and 2010, according to Gerald Roy, deputy inspector general for the U.S. Department of Health and Human Services.

More than 30 cases were opened last year on the heels of whistleblower suits by former hospice workers and others alleging Medicare fraud, according to federal officials who asked not to be named because many of the cases are sealed.

State scores low on wellness issues

A coalition of health and community advocates has issued a report card to Massachusetts indicating that when it comes to promoting a healthy lifestyle, the state needs to make improvements.

The Boston Globe reported that while the commonwealth remains a national leader in providing access to health care, it has plenty of room for improvement when it comes to prevention programs that help people avoid the doctor's office in the first place.

The Boston Foundation, one of the largest community foundations in the country, and NEHI, a nonprofit health policy institute based in Cambridge, scored the state on 14 areas of public health.

The state earned no A's and five B's.

The report recognized the commonwealth's efforts to build walking paths and bike lanes, promote farmers' markets and encourage workplace health programs.

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Record recovery in Medicaid fraud

A record $69 million in Medicaid fraud was recovered in Massachusetts during fiscal year 2011, surpassing the previous high of $55 million collected in fiscal year 2009.

The Attorney General's Office said that was a return of $18 for every dollar the office spent pursuing fraud cases during the fiscal year that ended June 30. The office's Medicaid fraud division had a $3.81 million budget.

At least $36 million of the recovered funds came from national settlements with pharmaceutical manufacturers and various settlements with pharmacies the state said were overcharging the Medicaid program for prescription drugs.

The tally includes a $9 million settlement with CVS Pharmacy, an $8 million agreement with GlaxoSmithKline, a $7.5 million settlement with Novartis and a $9.45 million recovery in pharmacy overcharges with Omnicare Inc.

Another settlement stemmed from a lawsuit filed in 2003 against 13 separate generic drug manufacturers.

Attorney General Martha Coakley estimates that her office has returned more than $200 million in Medicaid fraud in her first four years in office.

Harvard study: Most doctors will be sued

A Harvard study released Aug. 17 in the New England Journal of Medicine revealed that the majority of doctors in the U.S. will be sued at some point during their career, yet only about a fifth of such claims currently result in patient victories.

The report examined claims data for more than 40,000 doctors from 1991 to 2005. The researchers found that 7.4 percent of physicians had a malpractice claim brought against them each year and that 1.6 percent had a claim that led to a payment.

The study also found that neurosurgeons, obstetricians and other physicians who perform high-risk procedures will almost certainly be named in a malpractice case before age 65.

The likelihood and outcome of lawsuits varied considerably across other specialties, but even doctors in low-risk areas of practice, such as family medicine, had a 75 percent chance of being sued during their career.

Study: kids OK to play in heat, within reason

On the heels of a legal investigation into the latest hot-weather football-practice deaths, the nation's largest pediatricians group has issued new guidelines indicating that playing in steamy weather is safe for healthy children and teen athletes, as long as precautions are taken.

The advice from the American Academy of Pediatrics was released in August just a week after two Georgia high school football players died following practices in 90-plus degree heat. Authorities were investigating if the weather contributed.

The guidelines replace a more restrictive policy based on old thinking that kids were more vulnerable to heat stress than adults. New research shows that's not true – healthy young athletes can play even in high heat and humidity, within reason.

The guidelines include having an emergency plan with trained personnel and treatment available; giving kids about two weeks to adapt to preseason sessions, gradually increasing intensity and duration; educating everyone about signs of heat stress, including dizziness, muscle cramps, headaches and nausea; and ensuring proper hydration.

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Kids aged 9 to12 should drink about half a cup to a cup of water every 20 minutes; for teens, five or six cups per hour.

Bills, Rules & Regs

From Beacon Hill

Health council OKs school nutrition plan

The state Public Health Council in July approved regulations requiring schools to provide children with low-fat milk, fruit juice and water, ban soda and sugary drinks, require fresh fruits and vegetables to be sold in cafeterias, promote whole-grain breads and ensure that water is available to students for free throughout the school day.

According to the Massachusetts Public Health Association, one-third of Massachusetts school students are overweight, leading to a higher rate of absences and driving up health costs. The regulations, which stem from a law approved by the Legislature and signed by Gov. Deval L. Patrick in July 2010, are scheduled to take effect in the 2012-2013 school year.

The Department of Public Health is preparing documents to help guide schools as administrators face the task of implementing the new regulations, while the Department of Education and the John Stalker Institute, which works to educate Massachusetts school professionals about nutrition, are preparing training programs for school personnel.

Paid sick-day law could save $22.7M

New research from the Institute for Women's Policy Research shows that implementing a paid sick days law in Massachusetts would reduce the number of preventable emergency room visits and save taxpayers money.

The findings show that a paid sick days policy in Massachusetts would save $22.7 million in emergency room use, which includes $13.4 million in savings for public health services, such as Medicaid.

A broad coalition of public health advocates, small business owners and workers spoke out in July at a House Labor Committee public hearing about the benefits of the Massachusetts Paid Sick Days Act.

A separate IWPR report from 2009 calculated that Massachusetts businesses would save an average of $2.38 per worker per week, and that workers would collectively save $1.5 million annually in out-of-pocket health care expenses due to reduced risk of flu infection in the workplace. During the H1N1 epidemic, 8 million Americans reportedly went to their jobs with the flu, in turn infecting an additional 7 million people with the virus.

Massachusetts is one of a growing number of cities and states across the country considering paid sick days legislation. Connecticut adopted a statewide paid sick days law on July 1.

Municipal health bill signed by governor

Gov. Deval L. Patrick has signed into law municipal health insurance reforms that lawmakers have debated for years, providing a new way for cities and towns to make health plan changes.

Under the new law, which proponents claim will help cities and towns collectively trim their own costs by $100 million, municipalities may opt for an expedited collective bargaining process to negotiate new benefit plans for employees.

If municipalities and unions fail to reach agreement in 30 days under that process, the case would be submitted to a three-person review panel, including one union appointee, one municipality appointee and an appointee selected by the secretary of administration and finance, a post controlled by the governor. The panel would need to resolve matters within 10 days.

According to Patrick's office, municipalities will be able to use the process to adopt copayments and deductibles and other cost-sharing health plan features that are not higher than those offered by the state-run Group Insurance Commission.

Municipalities may also transfer employees into the state-run plan if it would result in at least a 5 percent savings compared to the local health care plan. The reform allows a portion of savings to be returned to employees and includes protections for retirees and employees with existing health concerns who are likely to incur higher copayments.

Regulators set rules to fight STD spread

Massachusetts health regulators for the first time have instituted rules that allow sex partners of patients infected with chlamydia to get a prescription for antibiotic treatment without seeing a doctor, The Boston Globe reported.

Chlamydia is the most commonly reported sexually transmitted disease in Massachusetts and the United States. The rules aim to thwart the rapid spread of the disease, which is especially prevalent among people under 25 and endemic in some Boston neighborhoods.

Chlamydia cases in the state have more than doubled, from roughly 8,700 in 1999 to more than 21,200 in 2010, according to the Massachusetts Department of Public Health.

"Right now, if you treat someone and cure them, they could literally be re-infected within hours or days from an untreated sexual partner," said Kevin Cranston, director of the infectious disease bureau at the state Public Health Department.

From Capitol Hill

Bill extends funds for hospitals training

Members of the House Energy and Commerce Subcommittee on Health have approved legislation to continue funding for the Children's Hospitals Graduate Medical Education Payment Program, Modern Physician reported.

The program provides federal funds to children's hospitals to help them maintain their graduate medical education (GME) programs that train residents.

Introduced by Reps. Joe Pitts, R-Pa., chairman of the health subcommittee, and Rep. Frank Pallone, D-N.J., the subcommittee's ranking member, the Children's Hospital Graduate Medical Education Support Reauthorization Act of 2011 will extend federal funding for the program at its current level for five years. About 40 percent of pediatricians and pediatric specialists receive training through the program, according to the subcommittee.

The panel also passed the Synthetic Drug Control Act, which would make illegal synthetic drugs that imitate the effects of drugs such as marijuana, cocaine and methamphetamines.

FDA: New label for anti-smoking drug

The Food and Drug Administration has announced that the label for the smoking cessation drug Chantix will be updated to address the effect of the drug on users with cardiovascular disease.

The new label will also include updated directions on how to select a "quit smoking" date, the FDA said.

The FDA announcement came after the agency analyzed the results of three clinical trials.

The three studies addressed two groups of Chantix users: those with cardiovascular disease and those with COPD, or chronic obstructive pulmonary disease, while a third study analyzed the time period for maximum effectiveness of the drug.

The agency reviewed a clinical trial of smokers with cardiovascular disease that showed that Chantix may be associated with a small increase in the risk of cardiovascular events – such as heart attacks – for those who took the drug.

However, the FDA noted that the "absolute risk of cardiovascular adverse events with Chantix, in relation to its efficacy, is small."

For users with COPD, the FDA reviewed a separate clinical trial which showed adverse events similar to those seen in studies for Chantix's initial approval, and the agency declined to add any new safety concerns.

The label will also be updated to instruct users to select a quit date and then start taking Chantix seven days prior, based on a third clinical trial studied by the FDA, to maximize the drug's effectiveness.

Chantix was approved by the FDA in 2006 as a prescription medication to help smokers quit.

But the medication has also been the subject of a number of suits and further analysis by the FDA.

In 2008, the agency issued an alert that "serious neuropsychiatric symptoms have occurred in patients taking Chantix." In July 2009, the FDA required the makers of Chantix and another smoking cessation drug, Zyban, to add a "black box warning" to their labels, highlighting the risk of experiencing serious mental health problems including behavioral changes, depressed mood, hostility and suicidal thoughts.

Not long after, plaintiffs began filing lawsuits, like the one filed by Linda Collins against Pfizer after her husband David committed suicide after taking Chantix for three months. Plaintiffs' lawyers have predicted that thousands of suits could eventually be filed.

— Correy E. Stephenson

New standards urged on blood transfusions

A government advisory committee has called for national standards on when a blood transfusion is needed.

There is variation nationally in how quickly doctors order transfusions, not in cases of trauma or hemorrhage, where infusing blood can be life-saving, but for other reasons.

Anemia is common in older patients, for example, who may get a transfusion as an easy boost instead of treating the underlying problem. And for open-heart surgery, there are steps surgeons could take to minimize blood loss instead of trying to replace it later.

All the variability shows "there is both excessive and inappropriate use of blood transfusions in the U.S.," advisers to Health and Human Services Secretary Kathleen Sebelius said. "Improvements in rational use of blood have lagged."

Blood banks welcome the idea, as they try to balance how to keep just enough blood on the shelves without it going bad.

"Better patient care is what's being advocated here," said Dr. Richard Benjamin, chief medical officer at the American Red Cross. "If a transfusion is not necessary, all you can do is harm."

Supreme Court tosses pro-tobacco order

The U.S. Supreme Court has affirmed a state order requiring four tobacco companies to start a smoking cessation program, rejecting a delay granted by Justice Antonin Scalia under a rarely used power last fall.

Scalia had allowed Philip Morris USA and three other big tobacco companies to hold off in making multimillion-dollar payments for a program to help people quit smoking in Louisiana.

Not only did the other justices say they were leaving the state court order in place, there were not even four votes to hear the companies' full appeal.

Scalia justified acting on his own by predicting that at least three other justices would see things his way and want to hear the case, and that the Court then would probably strike down the judgment against the companies.

The $270 million payment was ordered as part of a class action that Louisiana smokers filed in 1996. They won a jury verdict seven years ago.

The Court provided no explanation of its action.

Record $34 million verdict for New York med-mal victim

By Correy Stephenson

A jury in Orange County, N.Y., has awarded $34 million in compensatory damages to a woman left severely injured after her sodium levels were increased too rapidly.

The plaintiff was Diane Manganiello, a 42-year-old mother of five who suffered from chronic hyponatremia, said her lawyer Robert Winters, of counsel to Fein, Such, Kahn and Shepherd in Chestnut Ridge, N.Y.

According to Winters, when Manganiello arrived at Bon Secours Community Hospital in Port Jervis in January 2004, she should have been treated with a slow infusion of saline to adjust her sodium to a proper level. Instead, she was rapidly infused, resulting in osmotic demyelination syndrome.

As a result, Manganiello requires around-the-clock care at a brain injury treatment facility, has limited speech and cannot read a book, Winters said.

The $34 million verdict – said by the trial judge to be the largest verdict in Orange County history – will allow Manganiello to move home with her family, Winters said.

"This was a devastating injury that never should have happened," he said. "When people talk about putting caps on med-mal cases, this is one of the cases where you have to ask, 'What do you do when someone is this hurt? What do you do for them?' That's why there shouldn't be any caps."

Robert Rich, a partner at Feldman Kleidman & Coffey in Fishkill, N.Y., who represented Dr. Moinuddin Ahmed, the critical-care physician who treated Manganiello, did not return a call requesting comment.

But James Steinberg of Steinberg & Symer in Poughkeepsie, N.Y., who represented the hospital and nurse Rose Aumick, who treated the plaintiff, said, "The verdict is a travesty of justice. It doesn't speak to the evidence or the proof; the jury was completely overwhelmed by a highly sympathetic plaintiff."

Rapid correction leads to injury

Shortly after Christmas 2003, Manganiello began to feel sick, like she had the flu or a cold, Winters said. She was diagnosed with sinusitis but didn't seem to improve and when she struggled to be awakened one morning and "didn't seem like herself," she went to the emergency room at Bon Secours.

Initial tests found that Manganiello had a dangerously low sodium level of 99, Winters said. A typical sodium level ranges from 135 to 145.

"The issue when dealing with a patient with low sodium is to first determine whether or not they are suffering from acute or chronic hyponatremia," Winters explained, because the conditions are treated differently.

Ahmed rapidly infused Manganiello, Winters said, and saw her sodium rise from 99 to 126 over a period of just 14 hours. Nurse Aumick was named as a defendant because she accidentally accelerated the dosage, giving Manganiello even more saline than Ahmed had ordered.

Manganiello seemed better at first – she sat up in bed, ate some food and her family thought she would be coming home soon. But later that afternoon, she told her husband she felt sleepy.

"It was the last full conversation he ever had with her," Winters said.

Manganiello's condition went on a major downhill course, he said, and she lapsed into a coma. She suffered severe brain damage and now requires constant care.

At trial, the defense argued that Manganiello actually suffered from encephalitis, Winters said, even though multiple tests and lumbar punctures all came back negative for the disease.

Two of Manganiello's treating neurologists testified: one for the plaintiff, one for the defense. While the plaintiff's expert told the jury her injuries were a result of the rapid correction of hyponatremia, the defense expert contended she suffered from encephalitis.

Steinberg said that "every single doctor who treated [Manganiello] agreed she had encephalitis," with the exception of the plaintiff's expert. "Her chart said that despite the inconclusive brain biopsy, negative encephalitis panel and clear cerebral spinal fluid test, the diagnosis is encephalitis. And there was an MRI that showed encephalitis."

When he cross-examined the defense's neurologist expert, Winters went through the possible ways a patient can get encephalitis. Manganiello did not have herpes, did not suffer from an autoimmune disorder and did not have a bite from an animal. The only remaining possible source of the disease: mosquito bites. Winters first asked the expert what the incubation period following a mosquito bite would be, which ranges from two days to two weeks.

"Then I asked him: 'How many mosquitoes do you think were flying around northern New Jersey in December 2003?'" Winters said. Coupled with the negative test results, that exchange "had the capacity to create doubt for jurors that [Manganiello] suffered from encephalitis," he said, rebutting the defense's theory.

Four of Manganiello's caregivers also testified, as did three of her children, telling the jury about what life was like before their mother's injury and the effect it had on the family.

Winters also presented testimony about a life care plan for Manganiello with two different scenarios: remaining in the brain injury treatment facility or moving home with her family and receiving the same level of care.

Manganiello herself appeared at trial for the opening and closing statements.

Meeting the family

The four-week trial was spent predominantly on the plaintiff's presentation, as the defense only presented two witnesses, both experts. Winters had called Aumick, the nurse named as a defendant, during his case-in-chief, and the physician declined to take the stand.

After a day of deliberations, jurors asked to have the testimony of three expert witnesses read back, which implied to Winters that they were still debating liability.

Later that day, the jury returned its verdict, which includes $19.5 million in future medical expenses.

Jurors apportioned 60 percent of the fault to Ahmed and 40 percent to Aumick.

Steinberg said the defense plans to appeal on several grounds, but will first move to set aside the verdict and in the alternative, have it reduced to present value. **MMLR**

Plantiff Diane Manganiello and her husband, Andrew, prior to her injury.

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Save the Date

Awards Ceremony & Breakfast
November 4, 2011
Boston Marriott Copley Place
7:30-9:30am
Details on page 16

Verdicts & Settlements

Bacterial infection spreads to patient's eye

A 77-year-old woman made multiple visits to the hospital over a four-day period, first for "foot problems" with nausea, vomiting and diarrhea, and subsequently for intense pain in her wrists, which became swollen and hot, with swelling and streaking.

The patient was admitted with a provisional diagnosis of "polyarthritis questionably gout versus reactive arthritis." Fluid was aspirated from her left wrist and sent to the laboratory for a Gram Stain to be performed "stat." Continuing evaluation by staff indicated that "her presentation was consistent with gout although the process did not appear to involve any joints."

Five days after her initial presentation to the ER, an examination showed that her pupils were unequal and not reactive to light. A neurology consult revealed "a right dilated nonresponsive pupil and left pinpoint pupil with confusion." The neurologist opined that the administration of morphine could have caused a possible acute confusion state.

The Gram Stain was performed the next morning and identified Group G strep and Gram-positive cocci in chains. The doctors consequently suspected a septic emboli and septic arthritis and hypopion. Multiple antibiotics including penicillin were administered in conjunction with an infectious disease consultation.

The patient was subsequently transferred from the hospital to a tertiary facility and later discharged to a rehabilitation facility for approximately 30 days of treatment with intravenous antibiotics and rehabilitation for an additional two months. She is legally blind as a result of the septic microemboli.

The parties settled the case for $2.45 million.

Action: Medical malpractice
Injuries alleged: Blindness
Date: February 2011
Submitted by: Barry D. Lang, Newton; Dr. Max Borten, Gorovitz & Borten, Waltham (for the patient)

Student has brain hemorrhage after 20 hours in ER

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An MIT senior presented to the school infirmary with blood in his urine, a history of recent nose bleeds, petechiae on his legs and arms, and blood blisters around his mouth. He was sent immediately by ambulance to a local ER.

A complete blood count showed the patient had undetectable platelets. An attending hematologist and fellow diagnosed likely idiopathic thrombocytopenic purpura, or ITP, and ordered immunoglobulin and steroids. They did not order any platelets.

The patient remained in the ER for over 20 hours before he was admitted to the floor. About four hours later, he developed a headache that was treated with Tylenol with no improvement. While waiting for the results of a head CT scan, his head pain increased dramatically, he started to vomit and he became lethargic. The CT scan revealed a new, large left hemisphere hemorrhage extending into the subarachnoid space.

Neurosurgery was called and the patient was taken emergently to the OR for a left hemi-craniectomy and evacuation. Following surgery, the pressure in his brain remained high, so he was taken back to surgery for a left hemi-craniectomy expansion, further evacuation of his hemorrhage and a left temporal lobe lobectomy.

He was sent to a rehabilitation hospital where he experienced profound difficulty with word-finding, speech issues and basic math functions and had significant problems with the vision in his right eye.

With the help of therapy over the next few years, he was able to return to MIT and finish his last year of school with daily assistance and supervision. He continues to have vision problems and speech and language difficulties.

The patient expected to present expert medical testimony that the defendants were negligent in failing to give him platelets prior to the brain hemorrhage. The defendants were expected to show that platelets are only given for patients with ITP when the patient is actually having a brain bleed.

The case settled at mediation one week before trial for $2 million.

Action: Medical malpractice
Injuries alleged: Brain injury
Date: April 2011
Submitted by: Andrew C. Meyer and Robert M. Higgins, Lubin & Meyer, Boston (for the patient)

Timing of newborn's brain bleed disputed

In 2001, a woman was giving birth to her second child. The fetus' heart rate was noted to be slower than normal on multiple occasions during labor. The obstetrician administered oxygen to the patient but did not order a change in treatment or delivery protocol, eventually delivering the baby with use of a vacuum.

About 12 hours after the birth, a neonatology intern noted that the boy was blue, in respiratory distress and having persistent episodes of bradycardia. The intern notified the attending neonatologist but he did not come to evaluate the child.

The neonatology resident documented a low heart rate, a weak response to painful stimuli and poor respiratory efforts. The resident noted that she spoke with the attending, but nothing further was done for the child. As the boy continued to deteriorate over the next several hours, displaying "floppiness" and other signs of a possible brain bleed, the resident decided to transfer him to a children's hospital.

A CT scan showed a large, acute hemorrhage and brainstem compression. The child was rushed to the OR where he underwent an evacuation of the hemorrhage and insertion of a right frontal drain.

The child has been diagnosed with a significant brain injury. He has an aide in school and requires assistance in most of his daily activities.

The parents were prepared to present expert testimony that the obstetrician was negligent in failing to deliver the child more quickly and that the other doctors were negligent in failing to diagnose and treat his brain bleed shortly after birth.

The defendants were prepared to offer expert opinions that the drops in heart rate were normal and that the acute brain bleed did not occur overnight, but on the morning after birth.

The case settled for $3.5 million.

Action: Medical malpractice
Injuries alleged: Brain damage
Date: January 2011
Submitted by: Andrew C. Meyer and Robert M. Higgins, Lubin & Meyer, Boston (for the parents)

Man's vision damaged in post-crash surgery

The patient suffered multiple injuries in an auto accident. He sustained broken ribs, broken bones in his face, a broken orbital floor in his eye, the loss of four teeth, a collapsed lung and a lacerated liver.

He underwent surgery in which an implant was inserted to replace the orbital floor. While he was recovering in the post-anesthesia care unit, it was noted that he had lost light perception in his right eye. A CT scan was performed and showed that the orbital floor implant was bending upward and compressing the optic nerve.

The patient was promptly returned to the operating room, where the doctor removed the implant, trimmed it and re-inserted it. The patient continues to suffer from partial blindness in his right eye.

The defendants put forth the theory that compression of the optic nerve is a known complication of the surgery that cannot be prevented due the inability to visualize the optic nerve.

The case settled for $1.5 million.

Action: Medical malpractice
Injuries alleged: Partial blindness
Date: June 30, 2011
Submitted by: Michael J. Harris and Elizabeth N. Mulvey, Crowe & Mulvey, Boston (for the patient)

Doctors lacerate newborn's scalp

The patient was diagnosed as being fully dilated at 11 p.m. by one examiner. However, several notations establish that the cervix continued to rim around the presenting part until the cesarean section, shortly after 1 a.m.

Before full cervical dilatation, a fetal scalp blood sample was obtained by the attending obstetrician. At the time of the C-section, the pre-operative diagnosis was "arrest of dilatation at 9+ cm with failure to progress." The extension of the uterine incision was complicated by two scalp lacerations. The baby was born with facial palsy and a left nostril laceration, which required two cosmetic surgical procedures to repair, leaving a visible scar. The facial palsy subsided several weeks after birth.

A medical expert was prepared to testify that the descent pattern of the presenting part revealed that the mother should have been diagnosed as suffering from a secondary arrest of descent no later than 6 p.m., and that allowing the mother to continue laboring until past midnight was a clear deviation from the accepted standard of care, as was continuing to press the presenting part against an incompletely dilated cervix for over six hours.

The child, now 10, will require additional surgical intervention as she grows older.

The case settled for $750,000.

Action: Medical malpractice
Injuries alleged: Facial scarring
Date: November 2010
Submitted by: Dr. Max Borten and Sidney Gorovitz, Gorovitz & Borten, Waltham (for the parents)

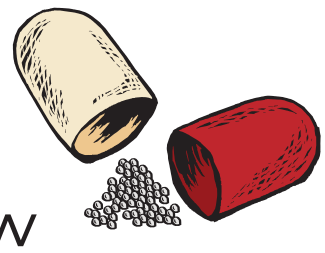
Verdict & Settlement Reports

Massachusetts Medical Law Report compiles the summaries of verdicts and settlements in this section 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 or 617-218-8152.

Good Medicine

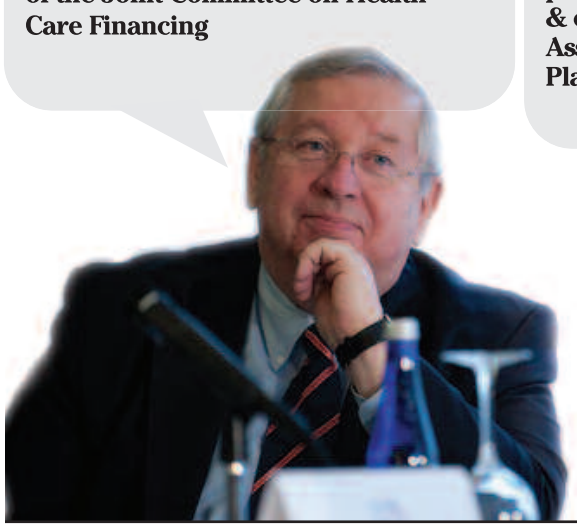
What doctors are talking about now



Q: What can health officials and medical and legal professionals do to obtain better enforcement of mental health parity laws to improve patient care in Massachusetts?

"We need to document through evidence-based research that putting resources into mental health and substance abuse will reduce the costs and improve the quality of care. Accountable care organizations and efforts to coordinate primary care must include addressing mental health issues. Parity must be established as part of the standard of care, and public and private payers must meet this standard. Given the use of medications in mental health treatment, coverage must include prescription drug benefits. It is also incumbent on mental health and substance abuse professionals to demonstrate the cost-benefit of mental health treatments to reduce the guesswork that now occurs among actuaries in estimating the value of mental health parity."

— Sen. Richard T. Moore, chairman of the Joint Committee on Health Care Financing



"Massachusetts health plans are complying with federal and state mental health parity laws. The level of utilization of mental health services in Massachusetts is substantially higher than the national average, and data from the state's Office of Patient Protection and the Division of Insurance has shown a high level of behavioral health visits and low number of external appeals – evidence that members have access to services and health plans are complying. Massachusetts health plans are consistently rated the best in the country for clinical quality and member satisfaction as well as for taking an integrated approach to mental health care. The issue is not compliance with mental health parity, but rather the availability of providers, which is a national problem that is not unique to Massachusetts."

— Eric Linzer, senior vice president of public affairs & operations, Massachusetts Association of Health Plans, Boston

"One issue is that treatment is only authorized if it's determined to be medically necessary, and the insurance companies determine that. There is no standard definition, so each company can interpret as it sees fit. This has placed an excessive burden on social workers, requiring them to participate in utilization and peer review to prove that services should continue. These reviews are one-on-one, 45-minute meetings with a mental health professional employed by the insurance company. The other issue is that there is no governmental body to regulate the laws, so insurance companies are setting the rules – no one's been appointed to ensure [their] administration. We've seen an increase in denials since right around the time the federal parity law was passed."

— Kristina M. Whiton-O'Brien, director of continuing education and clinical issues, National Association of Social Workers-Mass.

"To obtain better enforcement of mental health parity laws to improve care for patients in the Commonwealth, there should be an effort to increase funding for entities like the Disability Law Center: a private, nonprofit organization responsible for providing protection and advocacy for the rights of Massachusetts residents with disabilities. Additionally, individuals and groups should lobby the state Legislature to create a private cause of action with real financial teeth so that health insurers do not blatantly run afoul of the mental health parity law. The appeal procedures codified in [state law] currently do not offer a deterrent for corporate bad behavior."

— Frederic N. Halstrom, Halstrom Law Offices, Boston, handles medical malpractice and other personal injury cases

Mental health parity: Cast in law, not in practice

By Don Condie, M.D.

Massachusetts passed a mental health parity law in 2000, one of the first states to do so. This legislation requires any health plan to treat certain categories of psychiatric diagnoses in the same manner as they treat medical diagnoses, with no greater barriers to receive care.

In 2008, the federal Mental Health Parity and Addiction Equity Act was enacted, requiring insurers to follow federal law as well as state requirements if state law was judged to be more strict.

The push for parity – to treat "biologically based" psychiatric disorders the same way as medical conditions are treated for insurance coverage purposes – was prompted by restrictions placed on mental health services by managed care institutions.

The list of biologically based mental disorders in Massachusetts now totals 14, and includes such conditions as schizophrenia, depression, bipolar disorder, delirium and dementia, and rape-related mental or emotional disorders. In 2008, Massachusetts law was amended by adding eating disorders, post-traumatic stress, substance abuse and autism. (Massachusetts law also makes special provisions for children under 19, providing additional safeguards for "non-biologically based" mental, behavioral or emotional disorders.)

Despite the federal and state laws, however, we do not have parity. Discrimination against patients with mental illness, both in terms of access to care and limitations for ongoing care, still occurs. While the law and mental health care are complex issues on their own, let me offer a few examples that explain why I believe mental health parity is still lacking.

Doctor's Rx

A good example occurs with psychiatric patients in emergency rooms. A patient presenting with an acute medical condition such as a suspected heart attack is evaluated by an emergency room physician and admitted rapidly to an appropriately intense level of care – such as a cardiac intensive care unit.

For those presenting with psychiatric conditions, a "screening team" is called in to evaluate the patient, a process that can take several hours and may involve consultation with off-site supervisory clinicians more experienced than those on the mobile crisis team.

The team is then obligated to call to secure "prior authorization" for psychiatric admission – another process that can take several hours. For disputed cases, another step may be required, where a doctor-to-doctor phone call can add to the length of time a patient must remain in the emergency room after the ER evaluation has been completed.

The involvement of three separate entities, all redundantly evaluating the same patient, exists for no other specialty in medicine.

Another barrier to full parity has been the persistence of for-profit "carveouts." These are companies that hold contracts with private, non-profit insurance companies to manage behavioral health care. These "carveouts" have different sets of rules for approving various treatments for patients, making the process of patient care more confusing.

As a result, barriers continue to be put up that make it more difficult for patients to receive effective and clinically necessary inpatient and outpatient treatment. The companies and insurers have also been slow to follow models piloted by the Department of Mental Health for community support services that clearly work to reduce hospitalization for our most vulnerable patients.

Yet another issue limiting mental health services despite parity laws is the growing practice of requiring therapists to undergo lengthy and repeated phone interviews about their patients' progress before the insurance company will approve further treatment.

According to patients and therapists interviewed by The Boston Globe, and reports to the Managed Care Committee of the Massachusetts Psychiatric Society, these interviews have led to tougher criteria for additional visits and have been burdensome and intimidating. That has sometimes led to curtailed treatment and protracted appeals, despite the new parity laws.

Of all the medical specialties, psychiatry focuses most not only on the biology of disease but also on the effects of family dynamics and individual psychology on disease. All physicians know that family discord will make treatment of any physical illness more challenging, and psychotherapy, whether done by the psychiatrist or by an associated mental health professional, can be a necessary part of any comprehensive treatment plan.

The federal Departments of Labor, Treasury and Health and Human Services are responsible for implementing and enforcing the federal mental health parity law, making the complaint process cumbersome. For the Massachusetts parity law, the Division of Insurance is responsible, and the Massachusetts Psychiatric Society, along with other mental health treatment groups, has engaged in ongoing dialogue with DOI to make the case for enforcing parity laws more vigorously.

Physicians should be alert to difficulties their patients experience in accessing mental health services and should direct questions about limitations on those services to the Managed Care Committee of the Massachusetts Psychiatric Society and to DOI.

It is incumbent upon these agencies to renew their energy and commitment to the true spirit of the mental health parity laws. While the current environment is unnerving to providers and impeding our ability to provide care, it is, above all, affecting our patients, many of whom are not getting the equal and timely care they need and should be receiving.

That, I believe, is not what the laws intended.

Don Condie, M.D. is president of the Massachusetts Psychiatric Society, the state specialty organization of psychiatrists, with approximately 1,650 members.

State HIV bill would require doctors to offer screening

Continued from page 1

vacy protections are critical to encourage patients to consent to testing.

Here are some of the key aspects of the pending bills:

- They do not require written, informed consent for testing, as is currently required by law, but rather verbal informed consent. The patient's decision must be contemporaneously documented in the medical record.
- Patients who test positive for HIV must be referred for medical care and counseling.
- HIV-related medical information cannot be disclosed to third parties unless the patient consents in writing. The latest measure includes an exception for disclosures within the same facility to a treating provider "or for [Institutional Review Board]-approved research." The patient's written consent for releasing HIV information to a third party is separate from written consent for the release of other medical records.
- Testing costs would be borne by private insurers.

In an interview, Jehlen said the bills' goals are two-fold: "We want people to get treatment as early as [they] can and stop the spread."

According to Jehlen, the roots of the legislation can be traced to the Centers for Disease Control and Prevention's 2006 recommendation that diagnostic HIV testing and opt-out HIV screening, where the patient may decline testing, become a part of routine clinical care in all health care settings.

The June 2011 issue of the *Journal of the American Medical Association* reported that 24 states have changed their laws to adopt the CDC recommendations. As of January, 46 states and the District of Columbia had laws that were compatible with the CDC's guidance on consent and counseling.

Massachusetts is one of just five states where current law conflicts with that guidance some way, by requiring separate written consent for HIV testing.

Physicians debate the measure

Dr. Michael Wong M.D., an infectious disease specialist at Beth Israel Deaconess Medical Center in Boston, supports the legislation.

"I think overall it's a very good bill from a public health policy perspective. I think it helps eliminate a lot of potential stigma that's still tied to the whole written informed consent thing with HIV testing," he said. "And it makes it a lot easier for providers to actually bring up and talk about the subject with their individual patients."

The tests are neither expensive nor difficult to administer, Wong noted. A rapid test costs about $6, while standard tests cost around $20-$30.

He contended that the current law is burdensome because it requires physicians to review a standard bullet-point list of information with each patient, including information about the technology involved in the testing, culminating with the patient and physician signing a written document memorializing the exchange.

But Dr. Keith Nobil M.D., a primary care physician with The Family Doctors LLC in Swampscott, says the bill would make matters more complicated.

"The problem with the [pending] bill is it allegedly gets rid of written informed consent, but actually makes it more complex … because it's requiring that documentation be put in the medical record that the tests were offered and [whether] they were either accepted or refused. That to me doesn't seem too much different than having a written informed consent form that you have to go through and fill out with [a patient]."

Currently, the standard medical records release form allows a patient to keep portions of his or her records confidential, including information about HIV, STDs, alcohol abuse or psychiatric issues.

With the pending bill, "every time you have anything to do with HIV testing, whether it's offering it, a patient refusing it or having it done, then you're creating a separate 'record within a record,'" and how physicians would note that in electronic records or otherwise remains unclear, Nobil said.

That kind of record-keeping is a manifestation of what's known as "HIV exceptionalism," which keeps Dr. Paul Sax, an infectious disease specialist at Brigham and Women's Hospital in Boston, from supporting the bill.

HIV exceptionalism was the popular approach to testing among policymakers when the disease was first discovered, placing a higher priority on informed consent and protecting privacy rights than on case detection. For example, with other communicable diseases, such as syphilis, the state mandates partner notification and contact tracing – but not so with HIV.

"I was an HIV specialist in 1990, when the disease still presented a very poor prognosis," said Sax. "But what's really changed, by 180 degrees, is we now have effective treatment for HIV. And some of the policies that were put in place when the disease was first discovered are really no longer useful and [actually] hinder progress in the field."

He noted that the mandatory offer of HIV testing treats the disease differently than other preventive testing, where offers of testing aren't mandated, such as mammograms or colonoscopies.

Privacy concerns

Privacy is the most important concern expressed by people who call Gay & Lesbian Advocates & Defenders, said Bennett Klein, GLAD's senior attorney and AIDS Law Project director in Boston.

A previous version of the bill, S. 883, was debated at length during the last legislative session, Klein said. When the medical community spoke out against written informed consent, the HIV community compromised by agreeing to support verbal informed consent instead, he said.

"In my view, this is a bill that will not only increase HIV testing by implementing specific public health policies, but also is very cognizant of the fact that we have to maintain strong privacy protections if we're going to encourage people to get tested in the first place."

The Legislature's Joint Committee on Public Health held a hearing on the bill on April 5 of this year, where Klein expressed GLAD's support, along with the AIDS Project Worcester and the American Civil Liberties Union of Massachusetts.

At the hearing, Bill Ryder, Regulatory and Legislative Counsel for the Massachusetts Medical Society, raised several problems the Society sees with the bill.

Ryder questioned whether electronic medical records, built for national markets, have the capacity to comply with the pending state legislation.

In addition, the offer of HIV testing is mandatory unless there is evidence of the test having already been done. However, a patient's new provider wouldn't see any testing evidence without the patient's written informed consent. This is problematic, Ryder said, because for a period of time, the provider would be forced to treat the patient based on an incomplete medical record.

He also emphasized that the CDC recommendations were not adopted verbatim in the bills. The CDC does not recommend requiring separate written or verbal consent for HIV testing. Instead, the CDC advises that general consent for medical care should be considered sufficient to encompass consent for HIV testing.

The pending measures in Massachusetts, on the other hand, "support special legal status for HIV," Ryder said.

Ryder said his testimony was well-received by the public health committee. The measure is now pending before the Joint Committee on Health Care Financing. **MMLR**

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

Providers must prepare for upcoming HIPAA audits

Continued from page 1

or in early 2012, covered entities should prepare themselves now, Greene said.

On the privacy side, they should make sure they "have comprehensive policies and procedures that are up-to-date and reflect the issues of the organization," he said.

For example, an organization that bought a canned set of policies and procedures eight years ago might have since discovered that its biggest issues are the improper disposal of paper records and the inappropriate snooping by employees into electronic records.

If those issues aren't reflected in their policies and procedures, "that will not look good to OCR and the auditors," Greene said.

Covered entities should also ensure that they have conducted comprehensive training, especially for new staff.

"You don't want someone who has had exposure for nine months to personal health information simply waiting until the annual training comes around," Greene said. "And again, you want the training to reflect not just general HIPAA issues, but those specific to your organization."

Finally, he suggested that entities that have never imposed an internal HIPAA-related sanction may have a problem.

Not having issued a sanction "doesn't mean you have never had a HIPAA violation," Greene said. "Have a written sanctions policy that you have trained employees on so that they know the repercussions if they violate the privacy and security requirements."

Focusing on data security, covered entities should perform "a good risk analysis, which is the foundation of a HIPAA security program," Greene said, with a comprehensive risk management plan in place. "The risks identified in the analysis should be reflected in the reasonable and appropriate safeguards necessary to respond to those risks."

In a recent podcast, Susan McAndrew, the deputy director of privacy at OCR, indicated that "if an audit finds a major violation then it will be handled in the same way as an investigation," meaning that it could lead to an enforcement action, Greene explained. The audits "will not be limited to a strictly educational function." Narrowing the potential scope of audit candidates, McAndrew also mentioned that the audits will primarily, if not entirely, be conducted upon covered entities, not business associates as defined by HIPAA.

While that shortens the list of potential businesses to audit, Greene acknowledged that the odds of being audited remain low, given the number of covered entities.

"Think of it as losing the lottery," he said. "Even if the odds are low, some people are going to have their number drawn." **MMLR**

Questions or comments can be directed to the writer at: correy.stephenson@lawyersusaonline.com

Avoiding exclusion from federal health care programs

Continued from page 3

After their convictions, HHS-OIG exercised its permissive exclusion authority to bar the three executives from participating in federal health care programs for 20 years. Through the administrative appeal process, the duration was reduced to 12 years, and the executives are now appealing the 12-year term in federal court.

In the meantime, these health care industry executives are effectively barred from working in the health care industry. For the next 12 years, they may not work for any company that receives Medicare reimbursement money or any other federal dollars even though they were not found to know about or have committed criminal misconduct.

Proposed legislation

Given the government's successful defense of the Purdue Frederick matter so far, the aggressive exercise of permissive exclusion authority of officers and managing employees, as well as corporate entities, is likely to increase, and with new tools.

In February 2011, the Strengthening Medicare Anti-Fraud Measures Act was reintroduced in the U.S. House of Representatives with more than 20 sponsors. The bill expands the reach of HHS-OIG's permissive exclusion authority. The same legislation passed the House by a voice vote in the last Congress.-

According to the bill's primary sponsors, Reps. Wally Herger, R-Calif., and Pete Stark, D-Calif., the legislation expands the authority of HHS-OIG to ban corporate executives from doing business with Medicare if their companies were convicted of fraud after they had left the company. It also gives OIG the ability to exclude parent companies that may be committing fraud through shell companies.

This means that if a compliance officer moves to a new company simply to take a new job and not because he or she is knowingly leaving a mess behind, that compliance officer could still be excluded based on his or her prior employing company's conviction. As applied to corporate entities, the Act would seem to give HHS-OIG the authority to exclude Purdue Frederick's parent company, Purdue Pharma LP, based on Purdue Frederick's felony misbranding conviction.

As of August 2011, the Act was pending before the Health Subcommittee of the House Ways and Means Committee.

Maintaining effective compliance programs

In the current regulatory and enforcement environment, how do managing employees attempt to inoculate themselves against being infected by the misconduct of others and excluded from federal health care programs?

HHS-OIG's guidance points the way to a possible vaccine. "If the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct," the guidance advises, "OIG may consider this as a factor weighing against exclusion."

That could mean that ensuring the entity has an effective compliance program will weigh against, but not preclude, exclusion.

An effective compliance program is more than simply policies, procedures, hotlines, risk audits and governance structures. It is a way of being that permeates an entity's culture.

It is also a way to demonstrate why HHS-OIG should decline to exercise its permissive exclusion authority. That is, a managing employee could try to demonstrate that he or she exercised extraordinary care by ensuring the existence, implementation and monitoring of a comprehensive compliance program that, nevertheless, did not prevent the misconduct.

There are only two guarantees in life, and this is not one of them. But permissive exclusion authority should not result in the barring of unknowing managing employees who are genuinely and demonstrably committed to compliance.

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Intended Audience
This course is intended for physicians and allied health professionals.

Course Objectives
- Cite the eight most common medical mistakes that may lead to litigation.
- Describe strategies that may prevent the most prevalent medical mistakes.
- Explore best practices for office policies and medical record documentation to help mitigate risk.

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Course Developers
Henry Tulgan, MD, FACP
Reni Gertner, MPH, Editor Lawyers Weekly
Kathleen Bellisle, Manager of MMS Distance Learning
Thelma Tatten, Program Coordinator, MMS Distance Learning

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Medical mistakes: Learn to avoid the common ones

By Eric T. Berkman

A woman in her late 60s went to her primary care provider with stomach pains. The physician, figuring it was acid reflux, prescribed an antacid. But the problem didn't go away, and the woman came back repeatedly.

The doctor – who kept assuming that the patient's problem was acid reflux and continued to treat it that way – finally discovered that it was actually ovarian cancer.

How did he learn about it? When the family filed a medical-malpractice complaint after the patient died.

This is a true story, says Luke Sato, chief medical officer at CRICO/RMF, the captive liability insurer for Harvard University's medical institutions. And his organization had to settle the claim in what he describes as the "mid-to-high" range.

What went wrong in this case? The doctor engaged in what Sato describes as "diagnostic fixation," where a physician is so focused on a particular diagnosis that he or she fails to step back and consider other possibilities.

This happens largely because there's so much pressure on doctors to see as many patients as possible, spending only 10 to 15 minutes per patient, Sato explains.

"It's impossible [in this environment] to be as thorough as you want to be," he says. "So you try to address the immediate concerns. You prescribe something and say, 'Come back in a month.'"

Martin Foster, a med-mal defense lawyer at Foster & Eldridge in Cambridge, says that most of the doctors he ends up defending have tremendous caseloads.

"When I ask a physician what his caseload is, he'll often tell me he sees between 3,000 and 5,000 patients," says Foster, acknowledging the economic pressures that cause doctors to take on such a load. "And many subspecialists are seeing as many as 40 patients a day. … How can they see that many patients, maintain an appropriate medical record, make an accurate diagnosis and come up with a treatment plan they'll follow up on? It's just impossible."

Of course, diagnostic fixation and dangerously unrealistic caseloads are only two of the most common traps physicians stumble into that can lead to med-mal claims.

Here are six other big mistakes doctors should avoid making to protect themselves against medical-malpractice lawsuits:

1 Failure to properly supervise nurse practitioners and physician assistants.

As practitioners increase the number of patients they are seeing, they are relying more on physician assistants and nurse practitioners, says Anne Huben-Kearney, a registered nurse and vice-president of clinical risk management at ProMutual Group, the commonwealth's largest med-mal insurer.

She says her organization is seeing a rise in the number of claims stemming from physicians' failure to adequately supervise these professionals.

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For example, Huben-Kearney tells of a situation where a nurse practitioner in a primary care practice performed a PAP test on a patient that came back from the lab labeled "insufficient quantities." In this situation, the patient should have been called back in because the test was incomplete. But the nurse practitioner didn't repeat the test until the patient's next annual visit, when the same thing happened again.

"So two years in a row there was an insufficient quantity, no follow-up and no discussion with the [supervising physician]," says Huben-Kearney. "Once is pretty serious. But twice? Unfortunately, they missed a cervical cancer diagnosis. And as it turns out, the NP wasn't doing the test correctly."

The physician was ultimately named in the lawsuit because he was responsible for overseeing the NP. In fact, he was responsible for overseeing six NPs and PAs.

Huben-Kearney urges that every practice maintain written policies for supervision of NPs and PAs, laying out the scope of their practice, when they should involve a physician, and rules for the oversight of medical records and complex cases. They should also establish a ratio of no more than four non-physician specialists to each physician, no more than two of which should be nurse practitioners.

Sato says this should extend to residents and fellows in academic medical centers. He adds that sometimes the issue isn't the doctor's failure to supervise, but rather the failure to maintain open communication with other physicians.

"If a surgical resident or NP or obstetric midwife needs help, do you have a culture where they feel comfortable calling out and asking the attending physician to come in and take a look at the patient?" he asks. "We see fewer malpractice cases in cultures where people are open and speak up and there's more of a team-based approach as opposed to a hierarchical approach."

2 Failure to properly document decisions in the record.

Sato says one of the biggest problems he sees is when physicians become so afraid of being sued that they fail to write their opinions in the medical record. They think leaving their opinions out of the record will prevent those opinions from coming back to bite them.

But Sato says that's just not true.

"If nothing's there, it's worse. We can't defend you. Patients can do anything with [a blank record]. They can allege that you took a vacation or didn't care about them. But if there's something in there describing what you tried to do, even if you were wrong, it's still defendable."

This is particularly crucial when institutions and caregivers are at what Sato calls "the bleeding edge of medicine," where they may be deviating from the guidelines.

"You're not helping yourself by be-

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Medical mistakes: Learn to avoid the common ones

Continued from page 13

ing afraid to deviate from the guidelines when it seems necessary, since a reasonable physician would do the same thing," says Sato. "But it's important to document it so the jury can understand what you're thinking. Because if you don't, just imagine what the plaintiff could allege."

3 Failure to follow up on patients' diagnostic tests.

David Gould, a medical-malpractice defense lawyer at Ficksman & Conley in Boston, says an insurer he represents recently paid a large amount of money to settle a case on behalf of a doctor who ordered a nuclear-imaging stress test of a heart. The doctor didn't realize that the test results never came back. Accordingly, he failed to diagnose a serious heart condition in time.

This is a common scenario that represents a significant area of liability for primary care providers, Gould says. They order huge numbers of tests each day and are completely dependent on the system to get the results back to them. However, if the results don't come back, and there's no system in place to catch that, the physician is on the hook.

"The hope is that with the electronic medical record … those issues will be markedly diminished," he says, "but I don't think they can ever be eliminated."

The main point here is to have some kind of system in place, whether electronic or simply an accordion file sorted by date, says Huben-Kearney.

"Someone on staff has to have the responsibility of looking through the file on a daily basis, and saying, 'Oh, we were supposed to get this MRI back for this patient. Let's follow up and see what happened.'"

4 Failure to deal properly with noncompliant patients.

You might think that doctors would be off the hook when patients fail to follow their orders, whether such orders entail having a particular test, following an antibiotic regimen or even quitting smoking. But that's not the case because such patients often seek to displace their responsibility onto others.

"Noncompliant patients are like playing Russian Roulette," says Foster. "You never know when a patient who hasn't followed your instructions will turn around and say, 'It's not my fault.'"

For example, if a patient stops taking antibiotics because she feels better – and then develops a more serious infection – she may claim the doctor failed to adequately warn of the risk of stopping treatment.

And it doesn't matter whether a patient's claim succeeds. What matters is whether it's filed in the first place. Many insurers have a frequency threshold for such claims, and if a physician is a frequent flyer, he or she will be hit with a surcharge.

"Noncompliant patients pose a special risk for that kind of consequence," says Foster.

That's why ProMutual urges doctors not only to thoroughly document the specific instructions they've given, but also to use an informed-refusal form for patients who keep putting off a procedure or simply say they won't bother.

"The physician is saying, 'I feel so strongly that you need this procedure that I want you to acknowledge that you are fully aware and informed of the risks,'" Huben-Kearney says.

5 Failure to properly manage chronic-pain patients.

Most physicians are aware of the criminal and disciplinary risks of treating patients for chronic pain. But Foster points out that chronic-pain patients can also pose civil liability risks.

"If you treat a patient [with pain medication] and he or she becomes addicted, or an overprescription masks the ability to discern other medical problems or disease processes, it can result in a lawsuit," says Foster.

He adds that physicians can protect themselves through the use of a pain-management contract, where the patient agrees to take the medication in the manner the doctor ordered.

The contract can require lab testing to ensure the patient is taking the medication rather than selling it. The contact can also require the patient to use a single pharmacy, pick up the medication himself and prohibit the patient from calling after hours for additional medication.

"And let me say this: many providers in small internal medical practices might say, 'Well, I'll just refer these patients to pain-management experts anyway,'" Foster says. "But pain-management experts generally don't manage chronic pain on a day-to-day basis. So this is a reality that the general practitioner has to confront and manage."

6 Failure to choose words carefully in discussions with patients and in written records.

According to Gould, physicians are far too careless with the words they use, both in conversation and in writing.

For example, he tells of an elderly patient who died after surgery and whose family requested a meeting with the physician. At the meeting, the doctor said it had appeared that the patient was doing okay, but in retrospect, he wished he had done something sooner. And the same words were written in black and white on the chart.

"The family walked out of that meeting steaming," says Gould. "That's a big issue in this day and age – how [physicians] express themselves in writing and how [they] aren't cognizant of the risks their records carry."

This lack of circumspection can implicate fellow physicians as well. Gould tells of another case where one doctor treated a patient for abdominal bleeding after another physician had treated the patient.

"So the [subsequent treater] writes, 'In retrospect – those two words again – the cause of the bleeding was…' and gave a conclusion that was absolutely wrong," Gould recalls. "But that didn't stop a malpractice claim from being brought against the previous doctor."

Gould tried and won both cases, but the doctors still had to deal with lawsuits.

"A lot of cases are brought simply because one doctor" says something he or she shouldn't say, says Gould. **MMLR**

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

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The Physician's Corner

Avoiding medical mistakes and medical malpractice litigation

By Henry Tulgan, MD, FACP

There are few things more upsetting to a busy practitioner than being sued for malpractice because of a medical mistake. The state of Florida has recognized the importance of this issue by requiring the study of medical errors as a requirement for re-licensure, while many other states such as Massachusetts, Connecticut and Pennsylvania require risk management study, which includes course work on preventing medical errors.

The Institute of Medicine (IOM) and many other groups have studied medical errors that occurred at in-patient facilities and have presented us with some frightening statistics. In the IOM's landmark 2000 report, "To Err is Human: Building a Safer Health System," researchers found that more people die in hospitals each year from errors than from breast cancer or motor vehicle accidents.

The report identified four categories of medical errors:

Diagnostic errors, including:

- An error or delay in diagnosis.
- Failure to employ indicated tests.
- Use of outmoded tests or therapy.
- Failure to act on results of monitoring or testing.

Treatment mistakes, including:

- An error in the performance of an operation, procedure or test.
- An error in administering the treatment.
- An error in the dose or method of using a drug.
- An avoidable delay in treatment or in responding to an abnormal test.
- Inappropriate (not indicated) care.

Prevention-related failures, such as:

- Failure to provide prophylactic treatment.
- Inadequate monitoring or follow-up of treatment.

Other types of medical errors, which may include:

- Failure of communication.
- Equipment failure.
- Other system failure.

More than 10 years later, the prevention of medical errors remains at the forefront of improving the health outcomes of our patients and reducing the overall cost of health care. The types of errors discussed in the IOM report, both clinical and system-based, are still cited in current reports and findings.

It can be more challenging, however, to find equivalent statistical data in the outpatient, ambulatory setting. According to the Malpractice Insurers' Medical Error Surveillance and Prevention Study (MIMESPS), medical errors in the ambulatory environment were found to be complex, with multiple breakdowns in the system, particularly diagnostic errors. Medical malpractice attorneys and risk management experts point out mistakes that physicians make when they fixate on a possible diagnosis to the exclusion of other etiologies.

In addition, the patient caseload in primary care practices has increased, despite lessening numbers of them, and due to the growing shortages of subspecialists. This often causes delays in seeing patients, economic pressures and delegation of responsibilities to physician extenders (physician assistants and nurse practitioners), which adds to the complexity of care and decision-making. These complexities inevitably increase the risk of error.

However, as the prevalence of physician extenders continues to rise in the primary care setting, it is the physician's responsibility to supervise these professionals. Systems and processes for supervision must be in place, including a detailed policy manual defining the scope of various professionals' practice and parameters for the management and documentation of patient information.

MIMESPS, the study discussed above, also cited several other factors that play a critical role in medical errors, such as cognitive and system errors and the role of the patient.

To that end, it's important to carefully document information about any patient who does not follow a physician's recommendation, fails to take prescribed medications and/or refuses treatment. It's also important to document any refusals in the patient's medical record and use an informed refusal form signed by the patient.

Another example of non-compliance is the patient who is addicted to pain medication prescribed as part of a treatment plan. An effective risk mitigation strategy involves the use of a pain-management contract. Not only can this reduce the risk of potential litigation, but also it may help avoid potential disciplinary actions.

One of the most important things a physician must do to avoid a medical malpractice suit is to take care to communicate clearly with patients. As indicated previously, failure to communicate was identified by the IOM as a type of medical error. Effective interpersonal and communication skills are also included as one of the Accreditation Council for Graduate Medical Education (ACGME) Core Competencies. However, physicians can fall short when communicating with patients and their families, both verbally and in written records.

Many complaints reported to the Massachusetts Board of Registration in Medicine involve communication issues.

The Board recently highlighted the following suggestions to avoid the most common complaints from patients:

- Always tell your patients what you are doing as part of their care – and why.
- Follow up on test results immediately.
- Explain any delays in scheduling appointments.
- Communicate clearly – and listen.
- Ensure confidentiality.

Will we ever be able to eliminate all medical mistakes? Realistically, that seems unlikely. However, if we implement these suggestions, we may be able to reduce the number of medical errors and adverse outcomes while reducing litigation.

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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.

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1. "Diagnostic fixation" and unrealistic caseloads are two of the most common factors that can lead to medical malpractice claims.
   - ○ a. True
   - ○ b. False

2. Supervising physicians are protected from litigation due to medical mistakes made by their physician extenders (physician assistants and nurse practitioners).
   - ○ a. True
   - ○ b. False

3. A non-compliant patient may not sue his or her primary care provider (PCP) if he or she has an adverse outcome.
   - ○ a. True
   - ○ b. False

4. Pain-management contracts may help protect primary care providers (PCP) in potential lawsuits brought by patients who are addicted pain medication they prescribed.
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What are your topics of interest for future CME activities?

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Protecting your patients' electronic health information

Continued from page 1

health care information in Massachusetts, such as AIDS testing and substance abuse treatment, they might not be as up to speed on laws addressing security breaches.

"The federal government has increasingly imposed penalties for improper disclosure of information and we're seeing it on the state level as well," says David Szabo, a partner at Edwards Angell Palmer & Dodge in Boston. "There is increased concern [from] the government about protecting data such as Social Security and credit card numbers as well as following proper security practices."

In the event that information is lost or improperly accessed, Szabo notes that data breach notification laws might apply. If a patient record is breached because it is on a portable device that was lost, that might need to be reported both to the individuals whose data was on that device as well as to government agencies, he says.

Szabo recommends that medical practices review their insurance policies, as some policies are now being written to cover privacy risks.

"If a practice is making an investment in information technology, it's a good time to consider whether they have the right kinds of insurance coverage for the types of liability they might be exposed to," he says.

Dr. Larry Garber, medical director for informatics at the Fallon Clinic in Worcester, says there are several relatively simple steps – many of which are included in HIPAA – that can increase the security of patient data, including ensuring that personal computers are in a physically secure place, automatically logging off users after a period of inactivity, requiring passwords to access data and utilizing encryption programs when sending information.

However, he points out that underlying those measures is the need to educate employees about privacy policies.

Szabo agrees, noting that risks are created when employees are tempted to use information systems for unintended purposes.

"An example is a case involving a supervisor in a medical group who improperly accessed other employees' electronic medical records. It sounds like a law school exam question: How many issues can you find in that situation? These systems weren't designed so supervisors could see if employees were really out sick or actually had a doctor's appointment when they were supposed to be at work," he says.

Dr. Terry O'Malley, medical director for non-acute care services at Partners HealthCare System in Boston, says that practices need to have clear policies in place which are then enforced.

"If someone misuses access to data, then [he or she] should be fired. You need to have a book about the policies, but then demonstrate that you enforce them," he says.

Exchanging information

An increasing number of physicians have the option of using health information exchanges, which move and sometimes aggregate electronic information within a network, such as a community, region or health care system.

According to Schneider, every state currently has at least one health information exchange grant recipient. "We are at the fledgling stage of this, but they will be growing rapidly over the next few years."

These exchanges can create privacy issues. Schneider recommends that, when deciding whether to participate, physicians consult their state medical society or local hospital where they have admitting privileges to determine "if they endorse the protocols of the health information exchange," he says.

According to Garber, another thing for physicians to consider is the use of risk-sharing contracts.

With risk-sharing contracts, the practice is paid a fixed amount of money by a health plan to care for a certain population of patients. If at the end of the year the patients' bills are less than the amount the practice received, then the practice makes money. Otherwise the practice loses money, Garber explains. He said that this payment structure is becoming more common.

When physicians share the financial risk for patients, says Garber, they are then allowed to see all of the claims and bills for those patients.

"If one of those patients goes to see a specialist in Boston or gets a test outside of our system, I'll see those claims each week as we load them into our electronic records. I've even had patients go to Florida in the winter where they've needed care in an emergency room. When they return, they don't even have to tell me about it because I've already received that information in a standardized format," he says.

Risk-sharing contracts delegate some of the payer's administrative functions to the provider organization, notes Garber. At the same time, this moves the patient consent process, which typically would be handled by the provider organization involved in a health information exchange, back to the payer when a patient signs up for insurance.

However, Garber notes that this does not reduce either organization's responsibilities to maintain the privacy and security of patient data.

"There are numerous ways to securely connect these organizations, including a formal health information exchange, a direct VPN (virtual private network) connection, or secure encrypted e-mail. Direct (www.directproject.org) uses the latter and multiple EMR vendors have, or are planning to provide, support for it within their EMR."

Garber maintains that for practices that are large enough to negotiate good risk-sharing contracts with health plans, it is a worthwhile structure.

"We can take phenomenal care of those patients because we have more complete information about them," he says. **MMLR**

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