

Rx FOR EXCELLENCE NOMINATIONS DUE APRIL 1 – SEE PAGE 16

Physicians must prepare for new EHR regulations

By Eric T. Berkman

Doctors hoping to obtain a share of an estimated \$27 billion in federal incentive bonuses for implementing electronic health records would have to meet a wide range of new “meaningful use” requirements under proposed regulations released by the Centers for Medicare & Medicaid Services.

The two dozen benchmarks – which include such mandates as recording 50 percent of lab results and fulfilling 80 percent of patient requests for health information electronically by the end of 2012 – were issued by CMS on Dec. 30 as part of a long-awaited draft regulation defining “meaningful use” of electronic health records technology. The proposal was published



David Szabo

Jan. 13 for a 60-day public comment period.

Observers expect the final version will be quite similar to the proposed rules, and providers must be ready if they want to earn the maximum incentive payments.

“Depending on when you adopt ... the bonus could be higher,” said health care attorney David Szabo, a partner at Edwards, Angell, Palmer & Dodge in Boston.

At some point after 2015, he noted, “the chance to earn a bonus goes away and all you can do is avoid a [Medicare or Medicaid] penalty.”

The new regulation implements provisions of last year’s \$787 billion stimulus package, which called for incentive payments to eligible professionals and hospitals that achieve “meaningful use” of a certified EHR system starting in 2011.

The law left it to CMS to explain what “meaningful use” actually

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Family wins \$15M suit against Children’s Hospital physicians

What other doctors can learn from the case

By Justin Rebello

A Suffolk County Superior Court jury in Boston has awarded \$15 million to the parents of a young child who died following a series of complications from a catheterization procedure.

Jurors found that two doctors at Children’s Hospital Boston, Dr. James A. DiNardo, an anesthesiologist, and Dr. James Lock, the hospital’s former physician-in-chief, caused the death of three-year-old Jason Fox.

Jason died in December 2004, a year and a half after he was treated at the hospital for a birth defect. Jason’s father Brian, an attorney in Pennsylvania, said the basis for the

complaint was that Lock and DiNardo lied about their actions when treating his son, and attempted to cover up mistakes that were made during and after the procedure.

“We knew pretty early on after the procedure that Jason was very adversely affected,” said Brian Fox. “Before the procedure he was extremely interactive and engaging, then after he stopped talking, couldn’t walk independently. The doctors continued to insist he would just get better.”

Brian’s cousin, Sherman Oaks, Calif.-based James Fox, one of the attorneys that represented Jason’s family, said that his biggest chal-

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Few sure things for doctors in health care reform plan

Physicians gird for Medicare cuts, streamlining

By Julia Reischel

For physicians, Scott P. Brown’s surprise election to the U.S. Senate on Jan. 19 was a reminder: You can’t count on anything in health care.

“I think overall, health care reform is in a really dicey position right now,” said Kevin Pho, a Nashua, N.H., primary care physician who blogs about health care policy at KevinMD.com. “The components of it are changing on a daily basis.”

After the Massachusetts Republican barnstormed into the late Edward M. Kennedy’s Senate seat and destroyed the Democrats’ bulletproof 60-vote supermajority, the political winds behind two painstakingly crafted health care reform bills died. Thousands of pages of policy that medical professionals had been combing through to see their future were suddenly obsolete.

Whether Congress will salvage the remains of the bills that passed in November and December of last year is unclear.

But doctors and lawyers agree that some reforms are more likely to pass than others, and that the medical community should brace itself for several key changes in the coming year.

Here are a few things to prepare for:

More cuts in Medicare reimbursements

Any legislation that tackles health reform will likely reduce



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Medicare payments for some doctors, said Maria D. Buckley, an attorney in the Health Care and Life Sciences practice groups at Nutter, McClennen & Fish in Boston.

Medicare payments for some doctors, said Maria D. Buckley, an attorney in the Health Care and Life Sciences practice groups at Nutter, McClennen & Fish in Boston.

In fact, she noted, Medicare has already started to cut some payments routinely expected by specialists this year, in a regulatory change that did not require the blessing of Congress.

“Some changes [that] went into effect on Jan. 1 [say that] specialists can’t charge for a certain level of consultation, and other commercial payers have jumped on it,” Buckley said. “Some of the doctors were caught unaware.”

The change involves Medicare’s reimbursements for “con-

sultation codes,” which doctors use to bill Medicare when they confer with other physicians on a patient’s care. Since January, Medicare no longer reimburses doctors when they bill with consultation codes.

That, said Pho, who is a primary care physician, means that “specialists are feeling a little bit of a downward pressure on reimbursements.”

“[Medicare is] trying to focus more on primary care doctors,” he said. “That trend is going to continue ... If you want to control costs, eventually some services are going to have to be cut.”

Buckley said that some doctors are preparing for more cuts by researching how to survive without Medicare.

Administrative simplification

Experts also expect that whatever form reform takes, efforts to streamline recordkeeping will be involved.

“Administrative simplification deals with the enormous overhead of many insurance companies and the overhead they force physicians to have,” said Mario E. Motta, a Salem cardiologist who is president of the Massachusetts Medical Society. “Why does every insurance company need a unique form when [they all require] the exact same infor-

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The importance of what you say

My son's check-up at the pediatrician last week started the same as it usually does.

Dr. M. measured and weighed Brett, listened to his chest, checked his eyes and looked in his throat.

Thankfully, all was well.

"You have a great kid," he said. It's the next part I hadn't planned on. "And now you need to go to the lab for blood work."

Blood work? *Really?* I should have known it was coming, but somehow, I hadn't prepared myself – or Brett – for this. And I had barely a minute to get my act together.

On the way to the lab, I explained things to Brett, trying my best to downplay the notion that (yikes!) a steel needle was about to plunge into his arm and extract his blood.



"Dr. M. checked out all your outside parts, and now another doctor is going to check out your inside. It's going to be really cool. We'll

watch them take your blood and then they'll analyze it to see what's in it. There will be a pinch and then we'll just watch your red blood go into the tube."

In the packed waiting room, a more apprehensive bunch of patients listened in, enamored with Brett's series of questions:

"Mommy, what are they going to look for in my blood?"

"They are looking at your red blood cells, white blood cells, platelets," I said.

"Why are we still waiting? Why are all the other people waiting? Is the doctor going to look inside their blood?"

When they called his name, Brett jumped up and in we went.

He sat on my lap and the phlebotomist told me to hold his arm back, presumably to lessen the risk of him yanking the needle out.

I braced myself.

The needle went in. And even though it took a few more excruciating seconds than I expected, my son sat quietly.

Amazingly, he didn't cry, he didn't flinch.

At one point he did announce "I'm all done," but even when told they had to do it just one more time, he sat calmly and watched. When

it was over, Brett was beaming with pride as he exited with multiple Spiderman stickers.

I was in awe. I was proud of my brave little boy – and also, I was proud of myself.

Truthfully, I wasn't entirely surprised. This is a child who, somehow, likes getting a flu shot. He loves pretend doctor kits and giving my husband "an allergy shot" when he sneezes. (A physician in the making perhaps? He already looks the part in this photo.)

But even more striking for me is the way this experience illustrates the importance of not only what you say, but how you say it.

The more carefully a medical professional explains to a patient the details of a

procedure or treatment, the more likely the patient will walk in with a sense of ease. Clear expectations have the power to ground a person in even the toughest of moments.

Sure, Brett's just three years old, but the lesson still applies.

And years from now when Brett is the one in the white coat, I can see him comforting a patient and then saying with a smile: "You're all done!"

–Reni Gertner, MPH

Editor's Note



Photo by Udi Edni, Pix-R-Me

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INTEGRITY THROUGH COMPLIANCE

Patient wins \$4.5 million verdict in pain pump case

By Sylvia Hsieh

In the first verdict of its kind, a jury awarded \$4.5 million to an Oregon man and his wife for the loss of his shoulder joint after a pain pump was inserted following surgery.

The outcome is a boost to more than 300 cases already on file against several pain pump manufacturers, especially given that many saw it as the defendants' test case.

The claims against the defendant, pain pump maker I-Flow, are similar to allegations against other manufacturers: that they marketed the devices for an "off-label" use not approved by the Food and Drug Administration and failed to warn about the risks of cartilage damage.

After a request to consolidate the cases was denied, cases are now proceeding individually.

Tom Powers of Williams Love O'Leary & Powers in Portland, Ore., who helped try the case and has about 70 more pending, said this case shares common themes with others.

"There are three big strikes against all manufacturers. Every single one of them put the pain pump on the market without doing any research. All companies at various times tried to get approval and were denied or knew other companies with an identical product had been denied. And beginning in mid-2004 manufacturers started to see red flags from world-class orthopedic surgeons," charged Powers.

Ironically, unlike other plaintiffs' firms that are handling dozens of cases, this was the winning attorney's first and only case.

The attorney, John Coletti of Paulson Coletti Trial Attorneys in Portland, Ore., said he took it on because his clients were a "nice



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family" whose case fit within his firm's products liability and med-mal practice.

The verdict "sends a message that these are significant cases with serious injuries," Coletti said.

Multiple FDA denials

The plaintiff, 35-year-old Matthew Beale, underwent surgery in 2005 for a shoulder injury suffered during a flag football game.

At that time, orthopedic surgeons were using a pain pump that they inserted post-surgery that released anesthesia over two to three days. When it was finished, the patient would pull out and discard the catheter.

"The problem is the continuous exposure of cartilage to local anesthesia causes chondrolysis, which just melts away the cartilage until the joint is literally bone on bone," said Coletti.

During the two-week trial, Coletti demonstrated that the FDA had only approved the pain pump for use in the body for soft tissue surgery and had actually denied multiple requests by I-Flow to use it in joint surgery.

"First, I-Flow tried to get it approved for intra-articular surgery, and the FDA said no. Then they said proximal to the intra-articular space, and the FDA said no. Then they asked for approval in orthopedic surgery, and the FDA said no. Then they changed it to the synovial cavity, and the FDA said no. That's four times total they were told no by the FDA," Coletti said.

He argued that the company thwarted the FDA by marketing directly to doctors.

According to Coletti, doctors had been using a single injection of post-surgical anesthesia since the 1920s, and they had no idea that the pain pumps had not been approved for use in joints.

A string of doctors testified that had they known the pumps weren't approved they never would have used them.

Coletti also called a sales rep for I-Flow who testified that he would not have marketed the pumps for use in joint surgery had he known about the FDA denials.

While the defendant claimed that the doctor was to blame, Coletti argued that it was the surgeons themselves who began to notice the mysterious condition among their young, otherwise healthy patients.

"Doctors had never seen chondrolysis in their entire careers until they started using

pain pumps. And since they've quit using them, they have never had another case," Coletti said.

He blamed the company for failing to investigate safety concerns even as renowned orthopedic surgeons discussed their concerns at conferences and began conducting their own studies.

"Doctors started to speak amongst themselves and write articles to each other saying, 'We think it's these pain pumps.' The manufacturers were up in arms saying, 'How can they accuse us?' but they never did any studies themselves," said Coletti.

In November 2009, the FDA issued a statement saying that the pumps had never been approved for joint surgery and requiring the makers of the device and of the drugs used in them to warn of the risks.

Defense attorneys Eric J. Neiman of Williams Kastner in Portland, Ore., and Maynard Kirpalani, a partner at Wilson Elser Moskowitz Edelman & Dicker in Boston, declined to comment, citing a policy against commenting on pending litigation.

Kay Jackson, a spokesperson for Kimberly Clark, which acquired I-Flow in October, said the company will appeal the verdict.

But Coletti said if the company appeals he will appeal a pre-trial motion that denied him the ability to ask for punitive damages and put on evidence of adverse events that the company knew about but didn't report.

"They better be careful what they wish for," said Powers. "They could get a remand for a new trial likely to include punitive damages."

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Listening In

The news beat
of the medical profession

Massachusetts Health Data Consortium presents HIT conference

The Massachusetts Health Data Consortium presented "HIT '10: HIT at a Crossroads" on Feb. 5 at the Burlington Marriott Hotel.

The conference comprehensively examined the potential progress of the state's health care community from the 2009 enactment of the American Recovery and Reinvestment Act to the availability of billions of dollars to providers for the use of HIT systems beginning in 2011.

John Halamka, co-chair of the HIT Standards Committee for the Office of the National Coordinator for HIT, hosted a keynote presentation on health information

exchange (HIE) and the challenge of the proposed "meaningful use" requirements. (See "Physicians must prepare for new EHR regulations," on page 1.)

The presentation was moderated by Michael Doonan, Ph.D., assistant professor at Brandeis University and executive director of the Massachusetts Health Policy Forum.

Consortium CEO Ray Campbell served as moderator for a panel comprised of Richard Shoup, director of the Massachusetts eHealth Institute, and John Glaser, Ph.D., vice president and CIO of Partners HealthCare and

senior advisor to the National Coordinator for Health Information Technology.

That panel offered a look back at the impact of health information technology changes in 2009. MHDC Chairman Chris Gabrieli followed as moderator for a panel of thought leaders offering its predictions for the future of health IT.

The conference concluded with a panel of leading companies that will be a key part of helping the system achieve meaningful use of HIT and HIE. Karen Bell, M.D., senior vice president for HIT Services at Masspro, served as moderator.

Docs delay end-of-life talk with patients

Most doctors do not talk about end-of-life issues with their cancer patients when those patients are feeling well, a new survey has found.

The survey also indicated that physicians wait to discuss end-of-life issues with patients until all treatment options have been exhausted.

The study, published online in the journal *Cancer* in January and reported by The Los Angeles Times, found that of 4,188 physicians surveyed, 65 percent said they would discuss prognosis earlier in a patient's care. But fewer said they would discuss do-not-resuscitate status (44 percent), hospice (26 percent) or preferred site of death (21 percent) earlier in a patient's care.

Current guidelines from the National Comprehensive Cancer Network, a not-for-profit alliance



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of 21 of the world's leading cancer centers, say that such conversations should be initiated whenever a patient has been given less than a year to live, if not at diagnosis. Doctors gave various reasons for not following the guidelines. Some said they didn't want to dash patients' hopes; others said they wanted to continue treating patients.

In addition, said lead author Dr. Nancy Keating of Harvard Medical School, "There's at least some evidence to suggest that patients don't want to hear about these things."

But Dr. Ira Byock, director of palliative medicine at Dartmouth-Hitchcock Medical Center in Lebanon, N.H., argued that in addition to medical costs, the number of treatments and the degree of suffering rise when patients are not informed about end-of-life care options.

Study says higher copays for elderly don't help



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Faced with rising copayments, elderly patients visited their doctors less but ended up in the hospital more often and for longer stays, according to a new study in the *New England Journal of Medicine*.

The Boston Globe reported that Dr. Amal Trivedi and his colleagues from Alpert Medical School at Brown University looked at records of nearly 900,000 people over 65 who were enrolled in 36 Medicare managed care plans from 2001 through 2006.

Half the plans bumped up copays for outpatient care, nearly doubling the cost of primary care visits and increasing the cost of specialty care visits by 74 percent. In the other 18 health plans, co-

pays stayed the same.

Outpatient visits increased among both groups, but the increase was smaller in the group with copay hikes. Admissions and days spent in the hospital rose significantly for patients with copay increases. While copay increases would generate an extra \$7,150 in annual revenue for every 100 patients, the authors calculate it would cost the plans an additional \$24,000 in hospital costs.

"The main policy implication from our study is that increasing outpatient copayments is likely to increase total health care spending and adversely impact health for elderly patients," Trivedi said.

AG finds hospital clout drives health costs

Insurance companies in Massachusetts pay some hospitals and doctors twice as much money as others for essentially the same patient care, according to a report by Attorney General Martha Coakley.

The report points to the market clout of the best-paid providers as a main driver of the state's spiraling health care costs.

The Boston Globe reported that the yearlong investigation found no evidence that the higher pay was a reward for better quality work or for treating sicker patients. Rather, eight of the 10 best-paid hospitals in one insurer's network were community hospitals, which tend to have less complicated cases than teaching hospitals and do not

bear the extra cost of training future physicians.

Coakley's staff found that payments were most closely tied to market leverage, with the largest hospitals and physician groups, those with brand-name recognition, and those that are geographically isolated able to demand the most money.

The report did not identify insurers and providers by name, and Coakley declined to release the names of the highest-paid, saying she wanted to lay out system-wide problems, not blame individual organizations. More detailed information may come to light during Patrick administration hearings on how to control medical costs, scheduled to begin March 16.

Doctor accused of pain research fraud

Federal prosecutors have announced that they have filed a health care fraud charge against a doctor accused of faking research for 12 years in published studies.

Dr. Scott Reuben's data suggested that various painkillers, including the drugs Vioxx and Celebrex, provided certain post-surgery benefits.

Court documents indicate that the anesthesiologist has agreed to plead guilty in exchange for prosecutors recommending a more lenient sentence of up to 10 years imprisonment, a \$250,000 fine, and forfeiture of assets worth at least \$50,000 that Reuben received for the research.

Mental health issues rise in young

A new study has found that five times as many high school and college students are dealing with anxiety and other mental health issues as youth of the same age who were studied in the Great Depression era.

Though the study does not provide a definitive correlation, mental health professionals speculate that the stress of school and of a popular culture increasingly focused on the external – from wealth to looks to status – has contributed to the increase.

Led by Jean Twenge, a psychology professor at San Diego State University, researchers at five

universities analyzed the responses of 77,576 high school and college students who, from 1938 through 2007, took the Minnesota Multiphasic Personality Inventory. The results will be published in the *Clinical Psychology Review*.

Overall, an average of five times as many students in 2007 surpassed thresholds in one or more mental health categories, compared with those who did so in 1938. A few individual categories increased at an even greater rate – with six times as many scoring high in hypomania and depression.



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Association proposes major changes to psychiatric diagnoses

The American Psychiatric Association has proposed major changes to its diagnostic manual.

Under the changes, gambling would be added as a new behavioral addiction.

A new category of learning disabilities would be added, including problems with reading and math as new diagnoses. Another new diagnosis would be binge eating, distinct from bulimia.

The draft sets "autism spectrum disorders" as the diagnosis that encompasses a full range of autistic brain conditions, instead of differentiating between the terms autism, Asperger's and "pervasive developmental disorder" as physicians do today.

The draft also proposes diagnosing patients as being at high risk of developing some serious mental disorders – such as dementia or schizophrenia – based on early symptoms, without knowing who will develop a full-blown illness.

The proposal also sets scales to identify adults and teens at high risk of suicide, stressing that suicide occurs with numerous mental illnesses, not just depression. The association urges doctors to concentrate more on the severity of their patients' symptoms.

The APA expects that the changes could lower the number of patients defined as suffering from mental disorders.

Worker entitled to medical report

A three-judge review panel at the Department of Industrial Accidents has ruled that employees seeking workers' compensation are entitled to copies of medical reports generated by insurance company doctors.

After an employee injured his back at work, he received workers' comp benefits until the employer's insurance administrator appealed to a judge at the DIA. Before that hearing, the administrator had the employee examined by a doctor but failed to turn over the medical report and did not use it at trial.

When the judge denied the employee's benefits, his attorney appealed, arguing that he should have been allowed to see the report and use it as a foundation to cross-examine a second doctor.

The DIA panel agreed, stating that while the medical report itself may not be entered as evidence, "the opinions contained in the reports of other physicians are proper fodder for cross-examination, which ... safeguards the parties' right to challenge the opinion of the impartial medical examiner" hired by the DIA.



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Report: 34 states may ban health mandate

Lawmakers in 34 states have filed or proposed amendments to their state constitutions or statutes banning health insurance mandates, according to a nonprofit group that promotes limited government.

The American Legislative Exchange Council reported that many of those proposals are targeted for the November ballot.

Legislative committees in Idaho and Virginia endorsed their measures in January, while hearings on proposed constitutional amendments were held recently in Georgia, Missouri and Nebraska.

The intent of the mandate outlined in separate bills passed by the House and Senate is to expand the pool of people who are insured and paying premiums and thus offset the increased costs of insuring those with pre-existing conditions or other risks.

President Barack Obama and Democratic legislative leaders were working to merge the two bills when Republican Scott Brown won the Massachusetts Senate seat long held by the late Edward M. Kennedy, leaving Democrats one seat shy of the number needed to break a Republican filibuster.



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Bills, Rules & Regs



From Beacon Hill

Bill aims to mandate postpartum coverage

An Amherst Democrat is sponsoring legislation to require insurers to cover regular screening of women within a year after giving birth in an effort to combat postpartum depression.

The House Financial Services Committee held a hearing on the proposal, H. 3897, at the end of January.

Rep. Ellen Story said that the mandate on insurers to cover the condition wouldn't have much impact on insurance premiums, adding that screenings run from \$6 to \$7 and many physicians already perform them.

Postpartum depression – mental and physical suffering in the late weeks of pregnancy or in the months after childbirth – often goes undiagnosed until it has taken an excruciating toll, say advocates for maternal care. The condition affects 15 percent of Massachusetts mothers, according to a fact sheet disseminated by Story.

Dr. Janice Goodman, a professor at MGH Institute of Health Professions, noted that many women are afraid to admit depression because of stigmatization or their own lack of recognition.

But Sheila Sullivan, a Cohasset resident and administrator of a blog called Postpartum Awareness, said Story's bill ignores the effect of medication on women, which she said can often do more harm than good.

Gov. aims to control small biz health costs

The state insurance commissioner will now require health insurance companies to provide advance notice of any rate increases for small businesses and will reject those that he believes are "unreasonable or excessive," Gov. Deval L. Patrick has announced.

The Boston Globe reported that any increases that are "significantly higher" than the current level of medical inflation, 3.2 percent, will automatically be challenged by Insurance Commissioner Joseph G. Murphy, Patrick said.

The governor acknowledged that the plan was likely to upset some in the health care industry but said that health care costs are crushing small businesses, defined as those with 50 or fewer employees.

Patrick said he would also seek additional authority from the state legislature to limit the rate increases that providers are passing onto insurers.

Bill to punish docs for late death reports

A legislative proposal to punish physicians who fail to report a patient's death in a timely manner has been blasted by advocates for hospice and end-of-life care.

Sponsored by Rep. Brian Dempsey, D-Haverhill, H. 2040 would slap physicians and

their agencies with a \$1,000 fine and put them at risk of a license suspension if they do not report the death to a funeral director within 16 hours.

Rigney Cunningham, executive director of the Hospital and Palliative Care Federation of Massachusetts, said doctors who specialize in hospice care would be dissuaded from making death pronouncements because of a fear that they may miss the 16-hour deadline to report to a funeral director.

"It is central to the hospice philosophy to care for the family of the dying patient and that responsibility does not end with the patient's death," she said.

Cunningham said her organization represents 63 agencies that provide care to more than 21,000 terminally-ill patients in Massachusetts.

"Adding additional responsibilities to already demanding jobs would be completely burdensome to hospice staff and a poor use of nursing resources," she said.

House passes school nutrition measure

A long-dormant bill that aims to ban fatty snacks from Massachusetts schools has finally been approved by the House, according to The Boston Herald.

Under the bill, there would be no more sugary soda, cookies or candy bars, and fewer chips and sports drinks available to students. Schools would be encouraged to sell non-fried fruit and vegetables, whole grain products, nonfat or low-fat dairy products, noncarbonated water and juice with no additives.

According to a 2008 state Department of Public Health report, one-third of high school and middle school students in Massachusetts between ages of 10 and 17 were overweight or obese, outpacing national averages.

But versions of the bill have stalled for years, encountering resistance from the grocery lobby and those who have argued nutritional values should be instilled at home, not by government.

The bill now heads to the state Senate where, according to Rep. Peter J. Koutoujian, D-Waltham, who has been trying to push the bill through for eight years, "the chance ... is pretty strong it will pass."

Reps say small business health mandate unfair

The so-called fair share provision in state law requiring employers with 11 or more workers to offer health insurance to many of them has proven to be unfair to small businesses, two state representatives claim.

Rep. Smitty Pignatelli, D-Lenox, joined his Republican colleague, George Peterson of Grafton, to argue that small businesses are ill-equipped to calculate how many employees to whom they must offer health insurance. This problem is exacerbated by the law's provision requiring that part-time employees be converted into "full-time equivalent" employees for the purposes of determining how many workers must be offered insurance.

Pignatelli has sponsored a proposal to eliminate the requirement that businesses include part-time workers in fair share calculations.

Peterson said the status quo fails to account for employees who receive insurance through a spouse or family plan. He said the problem is particularly stark for temporary employment agencies.



From Capitol Hill

Doctors ask FTC for 'red flags' exemption

In light of a recent federal court decision, four national organizations representing dentists, physicians and veterinarians have called on the Federal Trade Commission to exclude health professionals from a controversial new regulation intended to combat identity theft.

A letter sent to FTC Chairman Jon Leibowitz by leaders of the American Dental Association, the American Medical Association, the American Osteopathic Association and the American Veterinary Medical Association is the latest challenge to the so-called "red flags" rule.

The FTC's interpretation of the regulation imposes a mandate on health professionals to respond to a detection of identity theft.

The organizations asked the FTC to make it clear that the rule will not apply to their members given the result of recent litigation brought by the American Bar Association against the FTC. In that case, the U.S. District Court for the District of Columbia ruled that lawyers should be excluded from the requirements imposed by the rule.

The decision follows wide criticism suggesting that the FTC's overly broad interpretation of the Fair and Accurate Credit Transactions Act of 2003 led it to create a rule that oversteps its authority.

In response to these concerns, the FTC postponed the rule's effective date to June 1, but it has not changed its position that the rule will apply to health professionals.

President's budget: More for Medicare, HIV, NIH, Health IT

The Department of Health and Human Services would see an almost 10 percent increase from the current fiscal year under President Barack Obama's proposed federal budget for fiscal 2011, according to Health Leaders Media.

Included in the budget are numerous provisions promoting healthcare reform, including additional funding for health information technology and comparative effectiveness research.

Other allocations include \$2.5 billion for health centers for underserved populations, \$250 million toward expanding the Health Care Fraud Prevention and Enforcement Action Team initiative, and \$79 million for an initiative focused on partnerships among rural health care providers.

The budget plan also earmarks \$3 billion for HIV/AIDS prevention and treatment; \$1 billion to improve children's access to healthy meals; and \$6 billion to the National Institutes of Health to support a range of new

cancer studies, including 30 new drug trials.

Further, the budget allocates \$222 million to expand autism research, \$169 million to the National Health Service Corps to place providers in medically under-served areas; and \$10 million for a federal employee workplace initiative to implement prototype wellness programs.

Of the \$900 billion proposed for HHS, the lion's share is targeted toward Medicare — \$489 billion, after recouping an anticipated \$722 million through revamped efforts to detect waste, fraud and abuse.

States would receive \$290 billion for Medicaid, which includes an additional \$25.3 billion to extend by six months the increases included in last year's economic recovery law. Both amounts represent about a 9 percent increase from 2010.

HHS delivers first health security plan

Department of Health and Human Services Secretary Kathleen Sebelius has announced the nation's first health security strategy, which focuses on protecting the health of Americans during a large-scale emergency.

The National Health Security Strategy establishes priorities for both government and non-government activities for the next four years. The plan and accompanying interim implementation guide outline 10 objectives to achieve health security, highlighting specific actions that the nation should take to prevent, protect against, respond to and recover from health threats.

Among the initial actions for the federal government are conducting a review to improve the system for developing and delivering countermeasures – medications, vaccines, supplies and equipment – for health emergencies; coordinating across government and with communities to identify and prioritize the capabilities, research and investments needed to achieve national health security; and evaluating the impact of these investments.

Senate nixes extension of Medicare cut

Senate Majority Leader Harry Reid, D-Nev., has removed from the Senate jobs bill a provision that would have extended a Medicare payment cut for seven more months, according to Health Leaders Media.

Earlier, the Senate had inserted several provisions into the bill affecting physicians, hospitals, nursing homes and other Medicare and Medicaid providers that expired on Jan. 1. With health care reform in the background, the jobs bill had appeared as a logical vehicle to move legislation ahead.

However, the American Medical Association criticized pushing off the proposed 21-percent Medicare payment cut as a "Band-Aid measure." The measure actually extended the current temporary fix – approved by Congress in late December – which expires at the end of February.

The AMA has been calling for a "permanent fix." In November, the House approved H.R. 3961, which would have replaced the current payment formula. In October, the Senate failed to approve a similar measure. In recent weeks, the AMA – joined by groups such as AARP and the Military Officers Association – has been calling for that change.

The health care provisions are expected to come back in separate "extenders bill" that the Senate is expected to consider soon.

The jobs bill that was released by the Senate Finance Committee included technical corrections for Medicare Part B therapy caps, extension of payment rules for long-term care hospitals, and an extension to COBRA premium assistance.

News from the Food and Drug Administration

By Kimberly Atkins

New FDA guidance would speed up medical device trials

The Food and Drug Administration has issued guidance on the use of a new statistical method the agency said could result in faster and less costly medical device clinical trials.

The guidance makes use of the Bayesian statistical method, which uses an algorithm that allows device makers to combine data used in previous studies with information from the newer study. This could make for smaller and shorter clinical studies, FDA officials said.

"This final guidance on the use of Bayesian statistics is consistent with the FDA's commitment to streamline clinical trials, when possible, in order to get safe and effective products to market faster," said FDA Commissioner Margaret A. Hamburg, M.D. "This is a terrific example of regulatory science in practice at FDA."

The Bayesian method has been used frequently by the FDA in other types of clinical studies, and the agency has approved a number of medical devices using the method.

The final guidance, titled "Guidance for Use

of Bayesian Statistics in Medical Device Clinical Trials," describes the method, design and analysis of medical device clinical trials; lists some of the benefits and difficulties of the Bayesian approach, and makes comparisons with standard statistical methods. The guidance also presents ideas for using Bayesian methods in post-market studies.

FDA moves to reduce radiation in scans

The Food and Drug Administration has launched an initiative aimed at reducing unnecessary radiation exposure from medical imaging procedures.

The measure is aimed at three types of medical imaging: computed tomography (CT), nuclear medicine studies and fluoroscopy.

According to the agency, these procedures are the greatest contributors to total radiation exposure in the country as they use much higher radiation doses than other radiographic procedures, such as standard X-rays, dental X-rays and mammograms.

"The amount of radiation Americans are exposed to from medical imaging has dramatically increased over the past 20 years," said Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological

Health in a statement. "The goal of FDA's initiative is to support the benefits associated with medical imaging while minimizing the risks."

The proposal calls for manufacturers of high-grade medical imaging machines to include safety controls that prevent patients from receiving excessive radiation doses. The FDA is urging manufacturers to install safeguards on their machines that automatically notify operators if they are using a higher-than-recommended dose.

FDA regulators are also creating best-practice guidelines that hospitals, clinics and imaging centers will have to meet to retain their imaging accreditation.

More on the initiative can be found on the FDA's web page in an article entitled, "Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging."

FDA to require data from cigarette makers

The Food and Drug Administration will for the first time require tobacco companies to disclose ingredients of cigarettes and other tobacco products.

It will also require companies to disclose the results of studies done on these products.

The new rules, which take effect in June, are part of a sweeping new law passed last year that allows the agency to regulate – but not ban – cigarette products.

In addition to requiring companies to disclose product ingredients, the law enables the FDA to order stronger warning labels on tobacco products and even demand changes or elimination of toxic substances.

The FDA can impose user fees on tobacco companies to pay for the regulations.

Agency officials will use the information to determine what ingredients may make cigarettes and other products potentially more harmful or addictive. The law requires the FDA to keep the data confidential to protect the companies' trade secrets, but the agency will disclose a list of potentially harmful ingredients to the public.

According to the American Cancer Society, cigarettes contain more than 60 known carcinogens as well as thousands of other chemicals and other ingredients. The new law will allow FDA scientists to study the effects of combinations of ingredients, something it was previously unable to do without a comprehensive list.

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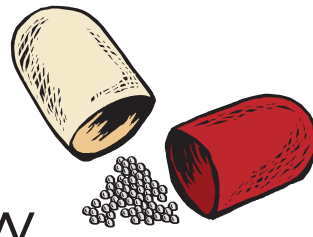
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Good Medicine

What doctors are talking about now



Q: Should marijuana be legalized for medical use?

"Marijuana as a medicine needs to be approached as many other medicines are approached: with thoughtfully-designed, randomized, controlled trials to determine safety and effectiveness. It is somewhat difficult to give a blanket, affirmative answer to the issue of legalization. The reason is that for several conditions that we have an important role in treating, there is evidence that marijuana constitutes a major risk factor for the illness. I'm actually just starting to do a study on this. It constitutes a risk factor, not necessarily for everyone, but for people who have a genetic or other vulnerability to the development of schizophrenic illness."

— **Theo Manschreck, M.D., president, Massachusetts Psychiatric Society**

"If Massachusetts enacts legislation that requires a physician's recommendation or prescription before an individual may legally possess or use marijuana, doctors will appear to incur the risks of civil liability for patient injuries, adverse interactions and contraindications. They stand exposed not only to civil liability and administrative investigations, but also to potential federal prosecution for distributing or recommending distribution of an illegal substance under federal law. What, if any, effective protections might be put into place by the Commonwealth if legalization is pursued is an open question."

— **Anthony E. Abeln, associate, Morrison Mahoney LLP, Boston**

"I do not support approving marijuana for medical purposes. In 2006, the FDA reiterated that smoked marijuana does not meet existing standards of safety and efficacy for modern medicine. Chronic smoked marijuana is detrimental to health – it is teratogenic; increases the risk of pulmonary, cardiac and bone diseases; compromises cognitive function; is addictive and is implicated in psychiatric conditions. Approval will send a wrong message that cigarettes and marijuana are safe, and the process of ballot initiatives for drug approval sets a dangerous precedent by circumventing FDA standards. Also, The Institute of Medicine has declared that smoking marijuana is not modern medicine and should not be recommended generally for medical use."

— **Bertha Madras, Ph.D., professor of psychobiology, Harvard Medical School**

"I have no first-hand knowledge of the benefits of medical marijuana. I am aware that in other states and countries, it has been used to reduce suffering and as palliative treatment for various neurologic conditions such as multiple sclerosis, severe chronic pain, neuromuscular disorders and seizures. Instead of relying on anecdotal evidence, I would support funding for studies and clinical trials to evaluate its potential uses and benefits, as well as its risks and adverse effects. If it is legalized for medical use in this state, I would need to increase my knowledge base to be able to make informed decisions about the use of the drug/plant in cases of appropriate neurologic care."

— **Alan Kurland, M.D., president, Massachusetts Neurologic Association**



Marijuana: Is it medicine or not?

By **Arthur Skarin, M.D.**

Americans have a split personality when it comes to marijuana.

A Gallup Poll last October found that support for legalizing marijuana reached an all-time high at 44 percent of the population. But that's still a minority.

Medical marijuana is quite different. Another Gallup Poll, taken six years ago, showed that 75 percent of adults were in favor of allowing doctors to prescribe the drug for medical purposes. In every category the pollsters measured – from political ideology to age to education – a significant majority were in favor of letting doctors prescribe marijuana to reduce pain and suffering.

Acceptance of medical marijuana, or the possibility that it could be a medicine, continues to grow. The Obama administration's action last year stopping federal prosecutions of those using the drug for medical reasons where allowed by state law altered the landscape.

Even the American Medical Association shifted its position, voting to study whether the drug should be re-classified from its current Federal Schedule One Controlled Substance classification (potential for high abuse, no legitimate medical use) to promote research into its medical effectiveness. Fourteen states now allow the plant to be grown and used for medical purposes, and five states permit retail pot dispensaries.

The issue has historical and contemporary relevance in Massachusetts.

Nearly 20 years ago, the state passed a Controlled Substances Therapeutic Research Act, to allow the Department of Public Health to examine the medical value of marijuana. Conflicts with federal law, however, prevented any research from being conducted.

Now, "The Massachusetts Medical Marijuana Act," sponsored by a dozen legislators, is pending in the State House.

Doctor's Rx

The purpose of this bill is "to protect patients with debilitating medical conditions, as well as their practitioners and designated caregivers, from arrest and prosecution, criminal and other penalties, and property forfeiture if such patients engage in the medical use of marijuana." The bill goes so far as to specify the maximum number of plants

(24) and usable ounces (8) of marijuana for qualifying patients that a primary caregiver can possess.

The medical marijuana debate continues across the nation. A psychiatrist, arguing in *The Wall Street Journal* for legalizing pot after New Jersey approved the use of medical marijuana, said the drug "has several unique medical applications" (he didn't specify what they were) and that for his patients, he's "more concerned about their consumption of booze than pot." The *New York Times* in an editorial on Jan. 13 called New Jersey's action a "rare piece of good news" and a "show of compassion for the chronically ill."

Opponents are speaking as well. Skip Miller, an attorney and chairman of D.A.R.E. America, a drug abuse prevention and education program, argued against legalization in the *Los Angeles Times*, saying that marijuana is "the most commonly abused illicit drug" in the country and "more teens are in treatment for marijuana addiction than for alcohol or any other drug."

Miller's words followed a 9-3 vote by the L.A. City Council to limit the number of medical marijuana dispensaries to 70 and restrict their hours. The action would shut most of the shops across the city, now numbering nearly 1,000. (A University of Michigan survey released in January showed that smoking marijuana among adolescents is more popular than ever, partly because the national debate over medical marijuana makes the drug seem safe.)

Some physicians say evidence is growing that the drug can benefit patients with neuropathic pain or nausea. However, as a clinical oncologist who has treated cancer patients for years and who has reviewed the use of marijuana for medical purposes, I have found little evidence to support marijuana as a medicine.

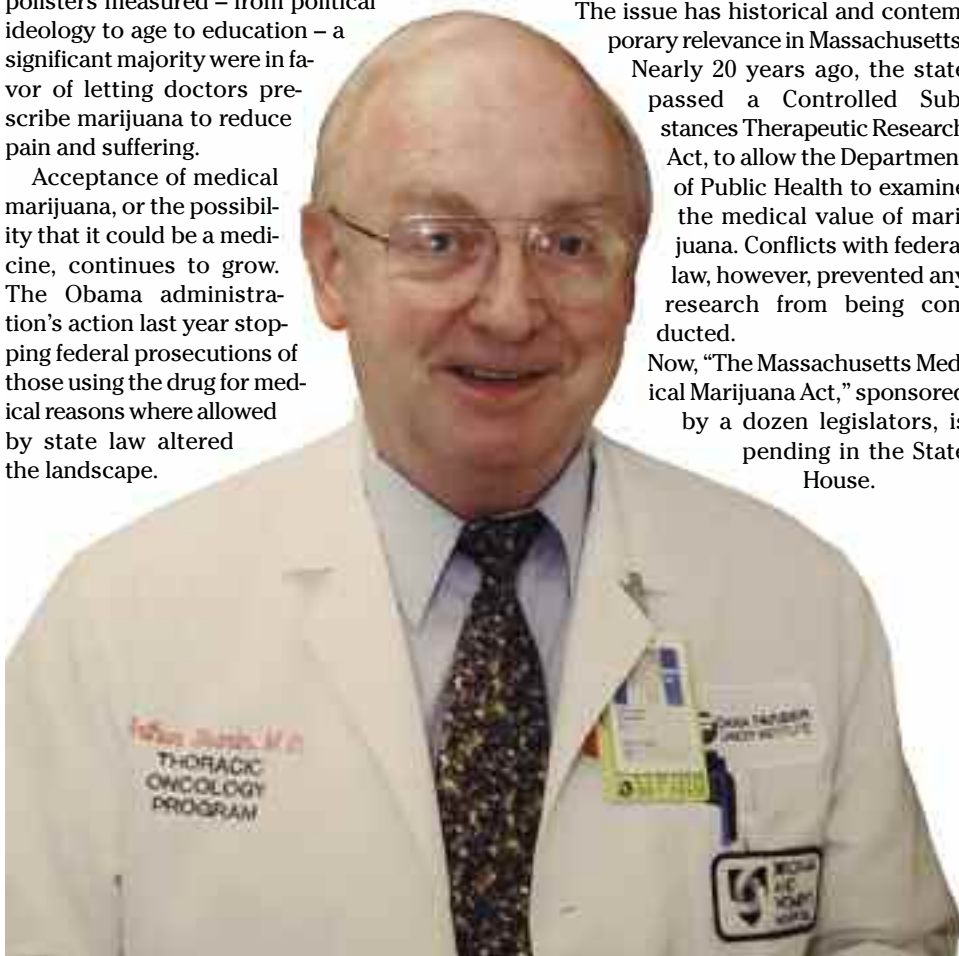
Two concerns are that clinical research is scant, and no established dosing regimen exists for any condition. I also note that the Food and Drug Administration has approved a synthetic form of medical marijuana, Marinol, available in pill form by prescription.

Support for medical marijuana may be growing, but the risks are high. The drug can lead to abuse and dependency. Marijuana can also affect judgment and inhibit motivation. Used in large amounts, it may cause pulmonary or other medical side effects. It can have psychiatric effects, deepening anxiety and depression and aggravating panic attacks. And it's often poorly tolerated, especially by older patients.

Also, the percentage of tetrahydrocannabinol (THC) is increasing, as production of the drug becomes more refined to improve its mood-altering effect. Finally, studies have shown that chronic marijuana users have a higher rate of lung cancer than those who smoke tobacco.

The media coverage and the legislative and regulatory debates will continue. Even as more states resolve the legal picture, the medical one remains cloudy and unconvincing. Some may see this as another choice between mainstream medicine and alternative therapies. But physicians, patients, regulators and lawmakers must examine the evidence, calculate the risks versus the rewards, and then ask the important question: Is marijuana really a medicine?

Arthur Skarin, M.D. is president of the Massachusetts Society of Clinical Oncologists.



Family wins \$15M suit against Children's Hospital physicians

Continued from page 1

lenge at trial was convincing jurors that such respected physicians would lie and deceive the parents of a patient. To do this, he structured his case around chipping away at the mystique surrounding the physicians.

Attorneys for the defense could not be reached for comment.

Preventing similar suits

Risk management consultant Jim Vaccarino, who practices in the Healthgroup at The Hays Companies, said he believes that the doctors were sued in the first place because Jason's parents did not feel they were open about the complications that arose from their son's procedure.

"The worse thing you can do is not be forthright with a family and then try to ... cover up your mistake" said Vaccarino. He noted that many physicians are prone to panic if a patient or his or her family accuses them of malpractice.

"You should speak to an advisor or a lawyer on your hospital's staff before you do anything," recommended Vaccarino.

Vaccarino said doctors can side-step potential med-mal lawsuits early by being completely upfront about the procedure (particularly a risky one, like the one undergone by Jason Fox), and providing all of the risks in writing.

He suggests establishing "a rapport with a patient [or] a patient's parents, and letting them know the risks, [including] long-term disability, death and complications, such as infection."

On the patient's chart, it is also essential to make sure each step of the procedure is outlined.

"If a doctor is accused of something, he might feel obligated to get rid of a part of the chart. ... [But] that [could be the] part another doctor [or expert will] point to and say you didn't deviate from the normal standard of care," Vaccarino said.

Martin Foster, a med-mal defense attorney at Foster & Eldridge in Cambridge, agreed

"The first thing people are going to look at in the aftermath of an adverse outcome is what did the [patients] know beforehand."

— Martin Foster, Foster & Eldridge

that the way the chart and accompanying documents are written is critical.

"You want a detailed narrative that explains what decisions you made, when you made them and why," said Foster. "Especially when it involves a relatively new or advanced procedure, the first thing people are going to look at in the aftermath of an adverse outcome is what did the [patients] know beforehand."

Birth defect

Jason Fox was born in July 2001 with a birth defect called Tetralogy of Fallot, which restricted the flow of blood through his heart. In Jason's case, the defect prevented his blood from carrying enough oxygen to his organs and limbs.

By the time he was two, Brian Fox said his son had already undergone seven cardiac catheterizations at Children's Hospital of Philadelphia to widen the arteries that carry blood to his lungs.

Doctors in Philadelphia finally referred Jason to Lock, a physician widely considered a pioneer in the use of catheterization to repair cardiac birth defects. On April 18, 2003, Jason went into Children's Hospital Boston for his second catheterization there.

Hours after the procedure, he suffered a seizure. According to a subsequent CAT scan, contrast dye had leaked into his brain.

After the initial seizure, two MRIs were



(AP Photo/Elise Amendola)

done to determine the extent of brain damage. The first MRI showed that a tiny piece of metal had become lodged in Jason's brain, which the lawsuit alleged was caused by carelessness with one of the instruments used during the catheterization. During the second MRI, Jason's heart rate dropped and doctors had to resuscitate him.

According to James Fox, the records included an adjustment in the dosage of epinephrine during resuscitation, which the complaint alleged had been botched.

The plaintiffs also uncovered a cardiologist's note from the hospital's ICU diagnosing Jason with "contrast toxicity due to high contrast load."

"They screwed with major parts of the record, especially the ICU note," charged James Fox. "That was a very damning indictment of Dr. Lock, and that note became the centerpiece of our liability argument against him."

Doctor on the stand

According to both James and Brian Fox, jurors informed them after the trial that they were displeased with the arrogance Drs. Lock and DiNardo displayed over the course of the trial.

James Fox said that his strategy was to get jurors to see that despite their admirable credentials (both men have been cited in hundreds of publications and written textbooks),

the doctors had made a mistake and simply assumed that their clout would get them off the hook.

Both doctors took the stand. James Fox said that he made it a point to cover even the smallest details of the procedure performed on Jason.

"I grilled [Dr.] Lock for a good day, going into a lot of detail," said Fox. "I asked how you set up the infusion pump. I asked him if he gave .3 ccs or .03 ccs. He kept getting more and more frustrated until he yelled out, 'I don't make mistakes!'"

After six weeks of trial and four days of deliberations, the jury awarded \$5 million for Jason's pain and suffering, \$5 million for his parents' loss of their child and \$5 million for wrongful death.

But James Fox said they won't see the entire \$15 million because the parties agreed to a high-low agreement during jury deliberations. He declined to elaborate on the specifics of the settlement. **MMLR**

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

Records altered

The pivotal documents in the case, according to James Fox, were the anesthesia record and Jason's medical record.

Fox said there were a number of inconsistencies that stuck out, including the fact that the anesthesia record had been signed off on by a physician who wasn't present during the administration of Propofol, an intravenously induced anesthetic. (The drug gained notoriety after allegations that Michael Jackson abused it prior to his death.)

Another inconsistency came to light in Jason's electronic medical record. One attending physician revealed during his deposition that he had made note of several key events during Jason's stay, but those weren't evident in the record. The physician insisted he made them electronically, and later provided a printed copy of the electronic record.

"When we saw it, it was identical to the printed record, but there were ten additional lines," said James Fox. "So we started looking at the electronic record for dates and times when the information was put in, and we could see on a number of occasions that doctors had logged in [afterward] and changed the information."



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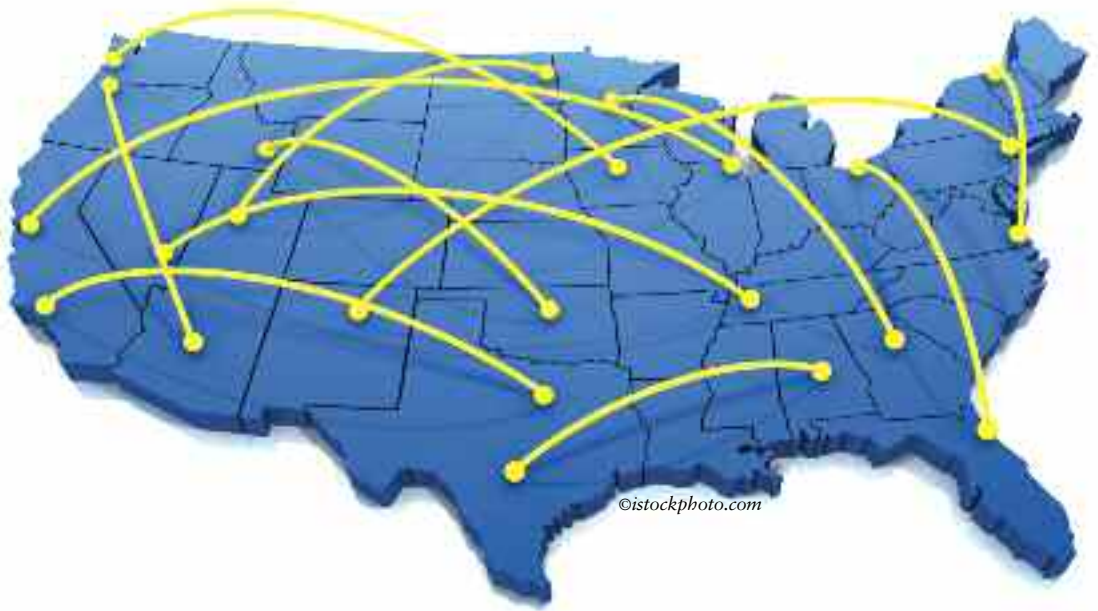
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From Courts around the Country



Oklahoma: Consulting physician not liable for malpractice

A physician-patient relationship is an indispensable element of a medical malpractice claim and therefore a doctor who was consulted about a plaintiff's pregnancy can't be sued, the Oklahoma Supreme Court has ruled.

The plaintiffs filed a medical malpractice claim against a non-treating physician who had a conversation with the treating physician concerning the plaintiff's history and complications.

The plaintiffs claimed that based on the non-treating physician's advice, the treating physician caused their daughter to be delivered prematurely, resulting in serious injuries.

The non-treating physician said that although he gave the treating physician his "informal" opinion, he was never asked to co-manage the mother's case.

The court held that the defendant could not be held liable because no physician-patient relationship existed.

"[The defendant] did not render medical advice to the plaintiffs; did not provide services to the treating physician on behalf of [the mother or baby]; did not receive a referral of [the mother or baby] for treatment or consultation; was not employed by [the treating physician] and had not been asked or contracted ... to provide medical treatment to [the mother or daughter]; and had not reviewed any work, conducted any laboratory tests, reviewed any test reports, pre-

pared any reports, or billed the plaintiffs. ...

"Further, none of the plaintiffs agreed that [the defendant] could treat [the mother or baby]. Even though [the treating physician] chose to rely on [the defendant's] opinion, [the treating physician] was free to exercise his independent judgment," the court said.

It concluded: "The facts before us fail to show that [the defendant] agreed to treat the plaintiffs or undertook treatment of any of the plaintiffs. Thus, there was not the physician-patient relationship necessary for a medical malpractice action."

The court cited similar rulings from other jurisdictions.

Oklahoma Supreme Court. Jennings v. Badgett, No. 105745. Feb. 9, 2010.

Iowa: Medical expert can't testify about cold medicine

A medical expert cannot testify in a products liability case that prescription cold medicine containing phenylpropanolamine (PPA) causes brain injury, the Iowa Supreme Court has ruled.

The plaintiff ingested "Aquatab C" and immediately felt pain in his head and numbness on his left side. In ensuing years he saw a battery of doctors for pain in virtually every part of his body, but no neurological abnormali-

ties were found in CT or MRI scans, and stroke was ruled out.

He sued the cold medicine manufacturer for products liability and hired an expert who would be the only person at trial to testify that PPA causes brain injury.

But the Iowa Supreme Court said that his testimony was not reliable to show causation.

"[The doctor] used one case-control study... in his general causation analysis. The study concluded that PPA was likely to cause hemorrhagic stroke in women, but ... in men showed no increased risk. ... [He] reasoned from this study [that] PPA can likely cause stroke and since [the plaintiff] likely suffered a 'stroke-like event,' this study tended to show a relevant causal connection. This study is simply not relevant to the case before us. It excludes men and ... does not describe an injury following PPA ingestion called 'stroke-like event' ... [and] as such ... cannot be the basis of any general causation opinion," the court said.

Further, "[s]pecific causation in toxic-tort cases examines whether the toxin at issue could have reasonably caused plaintiff's specific alleged injuries. ... Since [the plaintiff] has failed to reliably show [that] PPA is an external factor to be 'ruled in' to a differential causation diagnosis, it follows he cannot establish PPA caused his specific injuries."

Iowa Supreme Court. Ranes v. Adams Labs, No. 06-1428. Feb. 5, 2010.

Illinois: Med-mal damages cap violates state constitution

A cap on non-economic damages in medical malpractice cases violates the Illinois state constitution, the Illinois Supreme Court has ruled.

The case involved an infant who suffered severe permanent injuries due to medical malpractice at her birth.

The plaintiffs challenged the state's statutory cap on non-economic damages, arguing that the infant sustained disabilities that will "greatly exceed the applicable limitations on non-economic damages."

A trial court held that the cap violated the Illinois Constitution, and the state supreme court agreed.

"[T]he General Assembly's authority to 'alter the common law' ... is not absolute; it must be exercised within constitutional grounds. ... [T]he legislature's attempt ... to limit common law damages in medical malpractice actions runs afoul of the separation of powers clause."

The court noted conflicting opinions on this issue from other states.

Illinois Supreme Court. Lebron v. Gottlieb Memorial Hospital, No. 105741. Feb. 4, 2010.

Few sure things for doctors in health care reform plan

Continued from page 1

mation? Who does that benefit?"

He said that the reform bill passed by the U.S. House of Representatives in November contained many measures mandating simplification, but that the Senate bill, which passed on Christmas Eve, did not. Still, Motta expects that paperwork fixes will prove attractive as compromise measures in the future.

Buckley, who served as senior counsel for Blue Cross Blue Shield of Massachusetts before moving to Nutter, said that physicians should expect an increased emphasis on using electronic records.

"Clearly everyone is going to have to use electronic medical records," she said. "For doctors who haven't done that, the incentives and the pressures to do that will in-

crease." (See "Physicians must prepare for new EHR regulations," on page 1.)

Tort reform

Now that the Democrats are being forced to parley with Republicans, Motta expects that the prospect of medical malpractice reform is back on the table.

Tort reform measures were limited to small state-level pilot projects in last year's health reform bills, he said, because the Democrats have historically been opposed to such measures.

"Up until last year, the Democrats didn't even want to admit that liability was an issue," he said.

Now that the two parties must find common ground, Motta thinks that tort reform will be one of the first compromises to be made.

"Clearly, this is one of the lowest hanging fruits there is," he said. "The Republicans have said all along that if you want to get them on board, you must consider meaningful tort reform."

MMS isn't waiting for Congress to act, however. It is sponsoring a bill in the Massachusetts House of Representatives that would give doctors and patients a chance to uncover medical errors and reach settlements before any legal claims have been filed. The so-called "Apology bill" – formally known as "An Act Improving Patients' Access to Timely Compensation" – is currently being considered by the Joint Committee on the Judiciary.

"If that [bill] passes, that will completely change the landscape" in Massachusetts, Motta said.

On a federal level, however, Pho isn't as confident as Motta that medical liability measures will be a large part of any health care package.

"I wouldn't hold my breath," Pho said.

He pointed out that despite the new bipartisan veneer in Washington, it is likely that the Democrats will push forward with health care reform without meaningful input from Republicans.

"I think that the Republicans don't have a lot of influence right now," he said.

But Pho conceded that if Republicans do manage to shape a new bill, med-mal reform "might be a part of it."

MMLR

Questions or comments may be directed to the writer at: julia.reischel@lawyersweekly.com

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Physicians must prepare for new EHR regulations

Continued from page 1

means. (A separate proposal, issued by the Office of the National Coordinator for Health Information Technology on Dec. 30, lays out the technical standards for a "certified" system.)

According to the "meaningful use" regulation, providers who treat Medicare and Medicaid patients would receive incentives in three stages.

They would receive the first set of incentive payments if they meet all 25 benchmarks for "Stage I" of the phased-in implementation in either 2011 or 2012.

They would get further incentives for achieving increasingly rigorous (but not yet defined) benchmarks by the end of 2013 and 2015, after which non-compliant providers would face penalties. Early adopters who achieve compliance at all three stages could garner up to \$44,000 in incentives.

Many doctors and other health care providers agree that EHR adoption is a laudable and necessary goal. In fact, they say that CMS has worked hard to produce realistic benchmarks that utilize physician-friendly measures.

However, they also predict that the statutory and regulatory framework will make it both challenging and costly for solo and small-group practices – as well as small community hospitals – to meet the requirements in the proposed time frame.

Tough for small practices

Some of the benchmarks are ambitious, and will be especially difficult for smaller medical practices to meet, experts said.

"It's the smaller [entities] that will have greatest difficulties," said Ray Campbell, CEO of the Massachusetts Health Data Consortium.

For example, the regulation calls for all physicians to use e-prescribing 75 percent of the time by 2012.

David Harlow, a Newton-based lawyer and health care consultant, said that this won't be an easy task, noting that Massachusetts is considered a leader in e-prescribing even though only 10 percent of prescriptions are submitted electronically.

At the same time, other benchmarks seem pointless in light of what many physicians – especially specialists – do on a regular basis, Harlow said.

He referred to a requirement that elec-

"It's the smaller [entities] that will have greatest difficulties."

– Ray Campbell, MHDC

tronic reminders for preventative care and follow-up be sent to at least 50 percent of all patients age 50 or older.

"Why would, say, an orthopedic surgeon be sending out reminders based on age?" he asked. "That's really geared toward primary care, yet it's a measure that's required in order to get an incentive payment."

Campbell criticized Congress for putting more funds toward the rewards that occur *after* doctors achieve meaningful use, while not earmarking enough money to help physicians implement EHR systems in the first place.

Massachusetts Medical Society president Mario Motta, a Salem cardiologist whose own 10-doctor practice has adopted EHR, agreed.

"I'd never go back to the dark ages without [electronic records], but it's a huge expense," he said. "We're talking roughly \$30,000 to \$50,000 per physician [to start], and then you have [annual] maintenance costs that for higher-level systems – considering that the cheaper systems won't make the cut for 'meaningful use' – can range anywhere from \$8,000 to \$15,000 per physician."

Unlike most businesses that invest in infrastructure upgrades, doctors have no abil-



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ity to pass on their costs, Motta added.

"If you do everything right and somehow don't meet the benchmarks, you're stuck with the entire cost," he said.

Observers wonder if small providers who aren't prepared to make the financial investment or workflow changes might simply opt out of Medicare and Medicaid or gamble that come 2015, Congress will lack the political will to stand firm on noncompliance penalties.

"I'm assuming [Congress will] stick with [the penalties]," says Campbell. "But if the transition is messy and sticky and there are lots of failures, they'll have to revisit that policy. And I do think it will be messy and there will be a fair number of failures."

Meanwhile, the Department of Health and Human Services meaningful use workgroup is recommending that CMS reduce the number of benchmarks required at least for the first year. And other groups are expected to weigh in.

Some requirements not as tough

Despite the extent of the requirements, legal experts say that some of them might not be as tough to implement as it seems at first glance.

For example, the proposed regulation would require providers to have a system in place for electronic drug-drug, drug-allergy and drug-formulary checks by the end of the first stage of implementation, said Szabo.

But physicians aren't required to actually use the system at any point during Stage I – the system simply needs to be turned on during the provider's 90-day "meaningful use" testing period. The provider determines when that testing period will be, and during that time he or she must meet all Stage I criteria.

Under the regulation, doctors would also be expected to provide health information electronically to at least 80 percent of patients who request it, but Szabo points out that these requests are still highly unusual in the first place.

Meanwhile, though CMS expects providers to use computerized physician order entry (CPOE) for at least 80 percent of all orders during either 2011 or 2012, a provider would only need to demonstrate the capability to do so during his or her testing period, not the entire year.

That means that a doctor who manages to ramp up for, say, just the last three months of the year can still be a big winner, said Szabo.

Getting up to speed

Smaller practices need to get up to speed on how to implement an EHR system.

Harlow warns that a physician practice should not even attempt to roll out an EHR system if the physicians are only in it for the incentive payments. Though an effective system should ultimately start paying for itself through the internal office efficiencies it cre-

ates, a \$44,000 maximum incentive payment won't cover the implementation costs.

Additionally, said Campbell, successful implementation is at least as much about changing the way you practice and operate your business as it is about the technology itself.

That's exactly why it can take a practice up to six months to get used to an EHR system, said Harlow.

"During that time, physicians will work longer hours while seeing the same number of patients," he said. "They're learning to interact with the patient and the computer

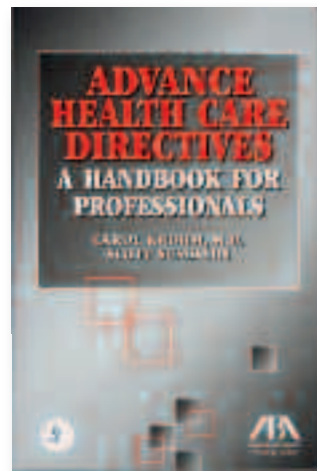
screen simultaneously and that's not the easiest thing in the world."

To make the transition smoother, experts suggest working with a health care management consultant, seeking advice from a peer who has already implemented EHR, and/or taking advantage of seminars offered by the MMS IT Committee on such topics as getting started, choosing a vendor and using the system.

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

Advance Health Care Directives



By Carol Krohn, M.D., and Scott Summers, J.D.

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Verdicts & Settlements

Jury finds nurses are not responsible for camper's death

A 14-year-old boy who was spending the summer at an overnight camp for children reported to the camp infirmary feeling faint, looking grey, and with cold hands and an irregular, pounding heartbeat. He felt dizzy while standing and although he felt better upon lying down, his irregular heartbeat was constant.

An hour after arriving at the infirmary the boy went into cardiac arrest. An hour and a half of resuscitation efforts at the camp, in the ambulance and at the hospital were unsuccessful.

The plaintiffs and their experts claimed that earlier intervention and hospitalization would have prevented the cardiac arrest or allowed for resuscitation and recovery.

The nurses contended that the camper died as a result of a cardiac arrest from an unknown underlying heart defect, hypertrophic cardiomyopathy.

They claimed that his medical records indicated he was a healthy boy with no medical issues and his symptoms, including the irregular heartbeat, were not severe for a supposedly healthy boy. They claimed that this was true especially because the



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boy's dizziness and color improved when he was lying down; he remained alert, oriented and conversant at all times prior to the cardiac arrest; and he did not have symptoms of chest pain or shortness of breath.

Besides the estate, the plaintiffs were the boy's sister, who was present when her brother went into cardiac arrest, and his parents, who were at the hospital when he was pronounced dead. The defendants were two nurses at the summer camp.

The demand started at \$6 million. At the suggestion of the defense, mediation was attempted but was unsuccessful. The demand never dropped below \$3.5 million.

Following a two-and-a-half-week trial that included expert testimony from a cardiologist, an ER physician and multiple registered nurses, the jury deliberated eight hours over two days before returning a verdict in favor of the nurses.

Type of action: Medical malpractice

Injuries alleged: Wrongful death

Date: Oct. 22, 2009

Submitted by: Ethan Warren, Warren, Hensley & Bowen, Boston

Woman's kidney slowly destroyed by forgotten clip

The patient underwent surgery in 1992 to remove her left ureter and ovary, where a tumor had been detected. Approximately 18 months later, she underwent a laparoscopy and lysis of adhesions and biopsy of the right ovary.

The patient subsequently underwent an additional surgery performed by a third doctor, which was an exploratory laparotomy with lysis of adhesions and right ovarian cystectomy and partial omentectomy.

During that procedure, visual inspection of the left kidney revealed that it appeared slightly enlarged. The right ureter was identified and was noted to be away from the surgical area during the operation on the right ovary. There was no mention made of the left ureter at that time.

Nearly 10 years later, the plaintiff underwent a CT urogram to evaluate complaints of left side abdominal pain. The plaintiff was found to have severe hydronephrosis and chronic obstruction of her essentially non-functioning left kidney, likely related to a surgical clip that the woman's urologist believed was placed "10 years ago."

At arbitration, the defense maintained that it would have been impossible to clip the ureter in 1992 without the patient having experienced immediate excruciating pain. On cross-examination, the defense expert admitted that one could have a partial obstruction without pain and that a partial ob-

struction could lead to a total obstruction and kidney failure years later.

The case ended with an arbitration award of \$450,000.

Type of action: Medical malpractice

Injuries alleged: Destruction of kidney due to misplacement of surgical clip

Date: October 2009

Submitted by: Gregg J. Pasquale, Melissa A. White and John P. Story, Keches Law Group, Taunton

Judge rejects claim of doctors' indifference

The patient, a former inmate in the state prison system, filed suit against the University of Massachusetts Correctional Health program, the Department of Corrections and his physicians for constitutional violations.

He contended that his contracted medical providers were deliberately indifferent to his ongoing pain during a one-year delay in hip replacement surgery.

The patient was scheduled to undergo a right hip replacement in August 2005, but his medical providers determined that he suffered from MRSA, precluding surgery.

On Feb. 23, 2006, a doctor at the Lemuel Shattuck Hospital determined that the plaintiff was free of MRSA. A year later, he underwent right hip replacement surgery, followed by physical therapy.

The patient then began to complain about left hip pain. Medical personnel gave him pain medications and his doctors determined in June 2007 that he required a left hip replacement. He underwent hip surgery in October

at the same hospital, followed by physical therapy.

The Superior Court found that none of the defendants could be sued for "cruel and unusual punishment."

It said that during the one-year period from the plaintiff's clearance from MRSA and his right hip replacement surgery, "the defendants took extraordinary steps to help the plaintiff minimize his pain, and attempted to remedy his serious medical condition, including adjustments in pain medication, diagnostic tests, a medical order to sleep on the bottom bunk, use of security doors to decrease the distance he would have to walk in the prison, room reassignments, stand-up lockers, an egg-crate mattress, crutches, canes, and knee sleeves."

The court found that the patient was allowed to carry certain pain medications to take them as needed. It ruled that as a matter of law, these actions defeated the plaintiff's claim of deliberate indifference in violation of the Eighth Amendment.

Type of action: Medical malpractice

Injuries alleged: Eighth Amendment violation

Date: December 2009

Submitted by: James A. Bello and Anthony E. Abeln, Morrison Mahoney, Boston

Woman suffers infection years after splenectomy

The patient underwent a splenectomy in 1995. Following the procedure, she received a pneumovax vaccination. She did not receive

a Hemophilus or Meningococcal vaccination.

In April 2001, the patient, then 35, began seeing a new doctor for her primary care. She saw the physician on two occasions and a nurse practitioner on four occasions. Neither of them recommended or administered a pneumococcal revaccination.

The plaintiff developed a pneumococcal infection that required a three-month hospitalization and a two-month stay in a rehabilitation residence. During her hospital admission, the plaintiff became septic, suffered organ failure and necrosis, and had to undergo partial amputation of her toes. She suffers from chronic infection and pain.

The patient contended that considering her asplenia, the standard of care required the defendants to revaccinate her.

The defense team argued that all of the visits were acute sick visits rather than annual preventative and wellness physicals. They claimed that this did not provide them with an opportunity to recommend or administer a pneumococcal vaccination.

The defendants also opined that a pneumococcal vaccination is not the standard of care, is not proven to be effective, would not necessarily have prevented the patient's variant of pneumococcal infection and had not been recommended by other non-party physicians.

The case settled for \$3 million after a second mediation.

Type of action: Medical malpractice

Injuries alleged: Failure to administer pneumococcal vaccine resulting in sepsis, organ failure and necrosis

Date: September 2009

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

Verdicts & Settlements—Continued on page 15

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Intended Audience

This course is intended for physicians and allied health professionals.

Course Objectives

- Describe the operational structure of Recovery Audit Contractors (RACs).
- Present potential numerical burdens of Recovery Audit Contractors (RACs) for providers.
- Identify for providers the possible fiscal and legal consequences of Recovery Audit Contractor (RAC) audits.
- Cite potential resources for providers to deal with Recovery Audit Contractors (RACs).

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Health care providers brace for Medicare audits

By Sylvia Hsieh

Health care providers are preparing for a national rollout of Medicare audits aimed at recovering money owed to the government due to incorrect billing by providers.

The Recovery Audit Contractor (RAC) program began in 2005 as a demonstration project in three states, and then expanded to more states – including Massachusetts – in 2007. It is scheduled for permanent rollout across the country in 2010.

RACs are private companies hired by the Centers for Medicare & Medicaid Services to audit health care billing records to identify improper payments. Improper payments can be overpayments or underpayments.

Given the success of the demonstration program – Medicare recovered over \$1 billion in overpayments – many health care providers are seeking legal advice on RAC audits and compliance procedures, as well how to appeal RAC claims.

Preparing for a RAC audit should be part of an overall compliance program, according to Vincent L. DiCianni, an attorney who now runs Affiliated Monitors, Inc, a company with offices in Boston and Westborough, Mass., that advises physicians and other practitioners on compliance matters.

'Bounty hunters'

The program began in California, Florida and New York in 2005, and then expanded to Arizona, Massachusetts and South Carolina in 2007. It was authorized under the Medicare Prescription Drug Improvement and Modernization Act of 2003.

CMS has published the schedule for introduction of the RAC program in the rest of the country. "Health care systems are really struggling with preparing for this because they know it's just a nightmare. During the demonstration program, it was very broad in that RACs were given all the data and told to go out and find errors," said Steve Lokensgard, a health care lawyer and special counsel to Faegre & Benson in Minneapolis, who previously worked as chief compliance officer to Allina Hospitals and Clinics.

RACs work on a contingency fee basis, receiving between 9 and 12.5 percent of improper payments they discover, so there is a big incentive to find billing errors.

Massachusetts is among the states with higher fees – 12.45 percent.

"They're bounty hunters on behalf of the Medicare program," said Jessica L. Gustafson, a partner at The Health Law Partners in Southfield, Mich., who co-chairs the firm's Medicare and RAC practice group.

She noted that of the misbilling identified by RACs during the demonstration phase, 96 percent was for overpayments and only 4 percent was for underpayments by Medicare.

Two types of audits

There are two types of audits: au-

tomated audits and complex audits.

The automated audit is based on data mining and automated analysis and usually involves clear errors, such as if a provider billed for duplicate procedures performed on the same patient on the same day.

Automated review began in Massachusetts in August 2009.

A complex audit requires an auditor to request medical records and typically involves areas susceptible to error based on the auditor's knowledge of the industry, said Lokensgard.

Complex reviews for coding errors were scheduled to begin in Massachusetts in October and November.

Reviews of records focused on whether the care that was billed was medically necessary are scheduled to begin in 2010.

"Once they get to the medical necessity reviews, I believe this is when individual providers will start to encounter the program in significant numbers," said Phyllis Flora, a health care attorney at Dwyer & Collora in Boston.

A medical necessity review may be triggered if Medicare suspects certain tests, billing codes or other services are being abused. This suspicion could be based on a higher use of those services in one area compared to the rest of the country, or on a rise in billing for certain codes.

In the past, Medicare has run reviews that focus on the medical necessity of powerchairs and ambulance services, Flora said.

She also said that durable medical equipment providers are specifically mentioned in the national rollout schedule and should be especially vigilant now in reviewing their record-keeping practices.

Gustafson predicts that Medicaid will step up audits under a parallel program similar to RAC called "Medicaid Integrity Contractors" (although MICs are not paid on a contingent basis).

Andrew Wachler of Wachler & Associates in Royal Oak, Mich., said he has already seen an increase in audits by private third-party payors, such as Blue Cross Blue Shield of Michigan.

Getting prepared

While large hospital systems appear ready for the permanent program, smaller physicians' offices that have more limited resources are less prepared.

"Our advice to clients of any size is you have to really pay attention to your compliance efforts. Now is the time to get your house in order," said Abby Pendleton, also a partner at The Health Law Partners in Southfield, Mich., who co-chairs the firm's Medicare and RAC Practice Group with Gustafson.

Within a 45-day period, a limit of 10 records can be requested of a solo practitioner, 20 records for a partnership and 30 records for a group practice, said Flora.

Health care providers are preparing for RAC audits by improving record-keeping and docu-

Continued on page 14

More appeals expected

As the RAC program expands across the country, health care providers are expected to appeal more "denials" – the term for a RAC claim for overpayment to a provider.

Although only a small percentage of denials were appealed during the demo phase, this is likely to change.

"In the permanent program, health care providers are going to be more interested in appealing and fighting these denials," said Steve Lokensgard, a health care lawyer and special counsel to Faegre & Benson in Minneapolis, who previously worked as chief compliance officer to Allina Hospitals and Clinics.

The appeals process has five levels, including a hearing before an administrative law judge and a fifth stage before a U.S. District Court.

It's important for providers to hire an attorney early on, as soon as they get a request for records, said Phyllis Flora, a health care attorney at Dwyer & Collora in Boston.

Jessica L. Gustafson, a partner at The Health Law Partners in Southfield, Mich., agreed.

She noted that hiring a lawyer before the hearing stage helps create a record for presenting and preserving evidence for the next level.

Attorneys who have represented health care providers in RAC appeals said they have had a high success rate.

"These appeals are winnable," said Gustafson, who co-chairs her firm's Medicare and RAC practice group.

Abby Pendleton, who co-chairs The Health Law Partners' Medicare and RAC Practice Group with Gustafson, said appeals can be made on two grounds.

Some appeals are based on the substantive merits of a claim – such as by presenting a physician's testimony as to why a patient was treated as an in-patient rather than as an out-patient.

Others are based on legal grounds – such as whether records are beyond the time frame of allowable requests or whether the standards for determining in-patient care were clear.

–Sylvia Hsieh

Health care providers brace for Medicare audits

Continued from page 13

mentation and training employees. Based on the demo phase, one area of focus will be in-patient hospital stays.

The vast majority of overpayments found by RACs in the demonstration phase – 85 percent – involved in-patient hospital stays, such as short stays or in-patient rehabilitation following surgery, said Gustafson.

Given these statistics, providers are reviewing their utilization review processes and whether physicians are admitting patients to the right area of the hospital, Wachler said.

“When providers take a close look at the records, maybe a patient met the criteria for an in-patient stay, but the documentation could be improved so that defending claims is easier,” said Pendleton.

In preparation for the RAC pro-

gram, Andrea Kloubec, senior director of compliance at Park Nicollet in St. Louis, Minn., has established a RAC committee and met with medical practitioners, such as in cardiology.

“If you look at one-day stays for congestive heart failure, should this have been in-patient or observation? If we found it should have been out-patient, we set up protocols for [determining] whether it met in-pa-

tient or out-patient criteria,” said Kloubec, who said there is software to help with these criteria.

Because her organization is a hospital, clinic, hospice, homecare and durable medical equipment provider, she also created five RAC response teams and completed a demonstration of a RAC request. She then tracked how long it took the teams to respond and what the outcomes were.

“We’ve timed every person in all stages of doing the RAC response” in order to find which areas could use improvement, said Kloubec.

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

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The Physician's Corner

Preparing for Recovery Audit Contractors (RACs)

By Henry Tulgan, M.D., FACP

In 2003, Congress, under Section 306 of the Medicare Prescription Drug, Improvement and Modernization Act, created a new program called the Recovery Audit Contractor program (RAC).

The new program is intended to detect and correct administrative and resource waste in the Medicare program.

It began in 2005 in California, Florida and New York, and expanded in 2007 to Arizona, Massachusetts and South Carolina. By 2009, the RAC program existed in 44 states and the District of Columbia. The program is set to roll out in the rest of the states in 2010.

Unfortunately, although hospitals started planning for the program immediately, many physicians are not as aware of the details as they need to be to ensure proper compliance.

There are four jurisdictions for RACs. They are not based on geography. For example, Massachusetts is covered by Diversified Collection Services located in Livermore, Calif., whereas the state of California is covered by a firm in Nevada.

Each RAC is staffed by nurses, therapists, certified coders and a full-time physician contractor who serves as the medical director.

RACs perform their functions on a contingency-fee basis and receive payment based on the

amount of improper payments they correct (both overpayments and underpayments).

Contingency fees are negotiated with the Centers for Medicare and Medicaid Services (CMS) and vary by region. Under a 2008 contract, contingency fees range between 9 and 12.5 percent.

The number of records a RAC may request is based upon provider type: The maximum number of records a RAC will review for inpatient hospitals and other similar facilities (inpatient rehabilitation facilities, hospices and skilled nursing facilities) is 10 percent of the average monthly paid Medicare claims with a maximum of 200 records. *Note: CMS has imposed a limit on the number of records RACs may request of 200 claims per 45-day period.*

The record limit request for other Medicare Part A billers is 1 percent of the average number of monthly Medicare episodes of care, again with a maximum of 200 claims.

Limits for practitioners (including physicians, podiatrists and chiropractors), based on the NPI submitted on claims are:

- Solo practitioners: 10 medical records per 45 days
- Small partnerships, consisting of 2-5 individuals: 20 medical records per 45 days
- Mid-size groups, consisting of

6-15 individuals: 30 medical records per 45 days

- Groups of 16 or more: 50 medical records per 45 days

- Other Part B Billers: 1% of the average number of monthly Medicare claims with a maximum number of 200 records per 45 days

However, these numbers will be increasing soon. From April through September 2010, the limit on the number of records that can be requested for review will increase from 200 to 300 for providers and suppliers who bill more than 100,000 claims to Medicare. In addition, RACs can request permission to exceed the limit in the latter six months of the fiscal year.

There are two types of audits:

- Automated audits rely on available data and usually involve clear errors, such as billing for duplicate procedures on a single day.
- Complex audits involve a request for medical records by an auditor and concern areas that may be susceptible to errors based on the auditor's knowledge of the industry.

Several organized medical groups have advocated on behalf of physicians to CMS that claims for evaluation and management of a patient's condition that reflect cognitive decision making should not be subject to review. These advocates also argue that RACs should not be allowed

to extrapolate the results of reviewing a limited sample of a provider's records to arrive at a higher overpayment amount. It is not clear if these attempts will be successful.

Some audits are focusing on whether short-stay hospital admissions are necessary.

Currently, RACs can review claims as far back as three years from the current date, as long as the claim was made after October 1, 2007. Physicians should prepare for RACs by conducting their own practice audits to ensure that all claims are coded and submitted according to Medicare rules. They should also visit RAC websites to familiarize themselves with the types of claims errors that have been identified.

Physicians must also be aware of the 120-day window to appeal adverse actions of an audit. This can involve a five-step process.

Several law firms have developed expertise in this area. When in doubt, early consultation with one of them may be advisable. Hopefully, the increased use of electronic medical records for documentation of services and of automated billing services with built-in safeguards will help protect physician practices from audit problems.

Although RACs are required to follow the same regulations as Medicare contractors from established programs, the fiscal and le-

gal consequences for unprepared practitioners could be severe. Careful preparation may save both a lot of apprehension and substantial costs.

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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, Mass.

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1. Recovery Audit Contractors (RACs) are located in geographic regions proximate to the covered states.
? a. True
? b. False
2. Recovery Audit Contractors (RACs) perform their functions on a contingency basis. .
? a. True
? b. False
3. Each Recovery Audit Contractor (RAC) is required to have a full-time physician contractor that serves as its medical director.
? a. True
? b. False
4. Small and large practices may have the same number of medical records reviewed.
? a. True
? b. False

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

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? Average
? Low

Will you make any changes in your practice as a result of participating in this CME activity?

- ? Yes
? No

If yes, please explain.

How do you rank the quality of this education program?

- ? High
? Average
? Low

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

- ? Yes
? No

What are your topics of interest for future CME activities?

Verdicts & Settlements

Continued from page 12

Doctors accused of inserting catheter too forcefully

The patient was a 59-year-old man who had a history of high cholesterol and smoking.

He began to experience cramping in his left calf after walking a short distance and was referred to a vascular surgeon for an evaluation.

He was diagnosed with moderately severe vascular occlusive disease. After a trial of the medication Trental, he had an absent pulse in his left foot. Testing revealed a distal superficial femoral artery popliteal occlusion.

The physician performed a surgical bypass. The plaintiff had had no urinary problems prior to surgery. After the spinal tap was placed, the circulation nurse attempted to place a Foley catheter, without success. The surgeon made a second attempt at passing the Foley catheter and noted in his operative report that it went in without resistance, producing a drop of fluid in the catheter. The 5cc balloon was inflated without resistance and the surgery was performed.

After surgery, the patient did not have any urine output. He was markedly distended and there was blood at the meatus. His rectal exam identified a boggy prostatic area with approximately 30 grams of smooth, benign prostate.

A cystoscopy revealed an area of extreme trauma past the urethral sphincter. No tract was identifiable past the prostatic urethra into the bladder; instead, an unidentifiable tract, through which the cystoscope was negotiated, continued from the bulbar urethra to the rectum. The scope was able to be passed from the urethra out through the anus.

Multiple attempts were made at passing the cystoscope from the penile urethra into the bladder, without success. There was a complete urethral disruption. A transvesical realignment was performed and a connection from the urethra to the bladder neck was re-established.

Newborn given overdose of anti-seizure drug

A baby was born by Caesarian section on Sept. 7, 2002, at 38 weeks gestation, after three days of labor induction due to difficulties in the pregnancy.

Two days later, the baby developed seizures with episodes of apnea and was transported to a separate hospital's neonatal intensive care unit.

Over the next two days, the newborn continued to have multiple seizures with tongue rolling, lip smacking, jerky uncoordinated movements of all extremities and apnea, despite treatment with the anti-seizure drug Phenobarbital. Doctors decided to administer a second medication, Dilantin, in hopes of controlling the seizures.

On Sept. 11, a nurse administered the medication to the baby by vein rather than intramuscularly, as had been ordered by the doctor. The baby developed apnea, mild bradycardia, distant heart sounds, weak peripheral pulses, poor tone, poor perfusion and cold extremities.

He was intubated and placed on a ventilator. His arterial blood gases reflected moderate metabolic acidosis. He received saline for his hypovolemia and hypoperfusion and medications to increase his



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blood pressure. He responded with an increase in his heart rate and blood pressure. His color, perfusion and oxygen saturation improved as well.

Blood tests showed an elevated level of

Dilantin, which gradually went down over a few days. The baby was then taken off the ventilator and was able to breathe on his own, and he was noted to have normal heart, kidney, liver and lung function.

Over the course of the next seven years, the child went on to demonstrate residual cognitive impairment and was diagnosed with autism. The parents claimed the injuries were a result of the Dilantin overdose.

The defense conceded that the baby had been given too much Dilantin but contended that it cleared quickly and the baby suffered no resultant harm. They further contended that the baby was brain-damaged long before the Dilantin episode, as evidenced by abnormal head studies performed prior to the overdose, and that his current condition was entirely unrelated to the Dilantin.

The case settled for \$6 million.

Type of action: Medical malpractice
Injuries alleged: Cognitive defects due to overdose of Dilantin

Date: January 2010

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

The patient underwent a procedure to repair the area and was discharged with a colostomy, which was later reversed. He has scars on his leg and abdomen.

The patient alleged that the surgeon and nurse deviated from the accepted standard of care when they used excessive force to insert the Foley catheter.

Both defendants claimed that the catheter was confirmed to be in the bladder before it was inflated because of the feel during the insertion, the length of catheter inserted and the return of urine. They argued that the perforation was a risk of the procedure.

The case settled for \$850,000.

Type of action: Medical malpractice
Injuries alleged: Failure to properly place catheter

during surgery causing perforated bladder and resulting urinary problems

Date: November 2009

Submitted by: Elizabeth N. Mulvey and Michael J. Harris, Crowe & Mulvey, Boston

Nurse, midwife fail to expedite C-section

On July 18, 2003, the patient, who was expecting her first child, was admitted early in labor to the hospital with intact membranes. She came under the care of a certified nurse midwife and obstetrical nurse that evening.

For at least four hours prior to delivery, the baby demonstrated fetal heart rate patterns indicative of a worsening fetal oxygenation status, particularly in the final two hours. Neither the nurse nor the midwife monitored the readings or called a supervising physician. The nurse did not check the maternal pulse to assure that the fetal monitor strip was recording the fetal heart rate rather than the maternal heart rate.

Five hours into the mother's stay, the nurse called the pediatrician, as she realized that she was recording the mother's pulse instead of the baby's heart rate for at least 40 minutes.

The baby was born limp and cyanotic with

no respiratory effort. She was intubated and transferred to the level II nursery, where she suffered seizures before being transferred to another facility.

She was diagnosed with hypoxic ischemic encephalopathy and status epilepticus. She was transferred to another hospital and stayed there until November, when she was transferred to another facility. She was eventually sent home and remains under the care of her mother.

The parents' experts were expected to testify that fetal hypoxia was present for a significant period of time prior to delivery and that there is no evidence of any alternative etiology for the HIE. The radiological findings indicate that the injury occurred before delivery.

The child, now six years old, suffers from spastic quadriplegia and significant cognitive, language, communication and motor delays. She will always be dependent on others for her daily activities, including personal hygiene, feeding, dressing and mobility.

The case settled for \$4 million.

Type of action: Medical malpractice
Injuries alleged: Hypoxic ischemic encephalopathy, permanent brain injury
Date: November 2009
Submitted by: Philip J. Crowe and Florence Carey, Crowe & Mulvey, Boston

Verdict & Settlement Reports

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

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

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7:30-9:30 AM

Awards Ceremony and Breakfast

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Hospital and Health Plan Administrators	Nurses
Risk Management Professionals	Attorneys
Insurance Company Professionals	Others

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The Leaders in Quality Award will honor professionals whose unique efforts have helped advance safety, quality and/or risk management for many patients and/or health care providers in the state.

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In 300 words or less, please describe what the nominee has done to deserve one of these awards.

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