

## New Congress sets sights on med-mal reform effort

### MMS urges alternative compensation model

By Kimberly Atkins

WASHINGTON – As soon as the 112th Congress opened its session, Republican lawmakers almost immediately seized on the chance to push medical malpractice liability reform efforts forward this year.

And after capturing control of the House and slimming the Democrats' majority in the Senate, GOP lawmakers focused on tort reform found the perfect legislative vehicle waiting for them: the health care reform law that is coming under increasing fire in Congress and the courts.

In the first month of the legislative session, House Republicans led a vote to repeal the health care law, and lawmakers introduced a medical malpractice reform bill that would, among other measures, limit punitive damages, cut attorney fees and shorten the statute of limitations for medical malpractice claims. That measure was advanced by the Republican-controlled House Judiciary Committee in February.

Rep. John Boehner, R-Ohio, said in his first press conference after being designated Speaker of the House that the law overhauling the health care system needed to be "repealed and replaced with common-sense reforms to bring down the cost of health insurance."

Other House lawmakers echoed that sentiment.

"Only reforms to the system on a federal level can address the current national medical liability crisis," said House Judiciary Committee member Rep. Trent Franks, R-Ariz., during a recent committee hearing on medical liability reform. "Unfortunately the massive health care overhaul that President [Barack] Obama signed into law last year did not meaningfully address medical liability reform."

Doctors in Massachusetts and around the country have expressed frustration with the current liability system, saying it raises health care costs, discourages candor between physicians and patients and thwarts safety improvement efforts.

"The system doesn't serve patients well, doesn't serve physicians well and doesn't serve the health care system well," said Dr. Alan C. Woodward, past president of the Massachusetts Medical Society and current vice chairman of the organization's professional liability commission.

But consumer rights and lawyers' groups have criticized Washington tort reform efforts, saying they would hurt injured patients.

"After repealing a bill that provided health insurance to over 30 million Americans, the next proposal from the new House leadership is to take away the legal rights of injured patients, remove any incentive to improve safe-

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## The importance of discussing end-of-life care with patients

By Jane Pribek

A few years ago, Dr. Prescott Lee, a geriatric medicine specialist in Peabody, discussed end-of-life care with a married couple in their late eighties who were both patients. They were "hearty octogenarians," and because they were so robust, it took him a while to get around to discussing it.

But he did. Surprisingly, he learned they'd never talked to a doctor about it previously. They later created advance directives, including Do Not Resuscitate orders.

Not long after that, the husband was diagnosed with aggressive cancer. He opted for hospice care and died peacefully.

While the wife is still grieving the loss of her husband, she has expressed her gratitude to Lee that he spoke to them about end-of-life care before her husband's illness was diagnosed.

"Although the situation was obviously very challenging, I think the decisions that were made beforehand helped make it easier, rather than her having to make tough decisions on the fly," Lee said.

The story illustrates the need for physicians to engage their patients in these discussions.

"The primary care physician should discuss end-of-life issues with all patients, not just with the frail elderly," said attorney Regina S. Rockefeller, a partner at Nixon Peabody LLP in Boston who concentrates in health

care law for providers. "Many end-of-life court cases have involved young people injured in accidents or who experience strokes, not people who have lived long lives."

### A non-reimbursable topic

On Jan. 1, a new Medicare regulation briefly took effect that listed "advance care planning" as one of the services that could be offered in the "annual wellness visit" for Medicare patients.

Just a few days later, President Barack Obama dropped that language from the regulation, with an administration official observing that, "This should not affect beneficiaries' ability to have these voluntary conversations with their doctors."

"It's true that you don't get reimbursed [by Medicare] for it," said Lee, "but it's still the right thing to do."

Dr. Stancel Riley, executive director of the Massachusetts Board of Registration in Medicine, said, "We would encourage everybody to have this conversation. Things can happen to all of us in the form

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## Medical mistakes: Learn to steer clear of the common ones

By Eric T. Berkman

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

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

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

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

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

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

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

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

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

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

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

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# 'Rx for Excellence' event to highlight medical community's finest work



Today, I am excited to open the nomination process for our 4th Annual Rx for Excellence Awards.

Again this year, we are honoring professionals in

two categories.

Our Heroes from the Field are the unsung heroes of their professions. They are the doctors whose patients regard their bedside manner highly, the practice managers who ensure that their offices run smoothly, the nurses who spend more time by a sick patient's bedside than the rest and the health

care attorneys whose clients consistently sing their praises.

Our Leaders in Quality are pioneers who have created and led efforts to enact change for large groups of patients and health care providers who improve patient safety and quality. They include hospital quality managers who have developed innovative safety programs, government officials who focus on improving patient safety and health care access, and physicians whose work in their field demonstrate best practices.

If you know anyone in our community who fits the bill, please nominate them today. You can find the nomination form at: <http://www.surveymonkey.com/rxforexcellence2011>

## Editor's Note

You can also go to our website at [mamedicallaw.com](http://mamedicallaw.com) or to page 16 of this newspaper for more information. All nominations are due by May 1, 2011.

Please be sure to mark your calendar for our 2011 Rx for Excellence Awards Ceremony and Breakfast, where we will honor all of our winners, on Friday morning, Nov. 4.

We look forward to receiving your nominations, and to seeing you in November.

As always, if you have any questions about Rx for Excellence or anything related to Massachusetts Medical Law Report, please don't hesitate to contact me at [reni.gertner@mamedicallaw.com](mailto:reni.gertner@mamedicallaw.com).

— Reni Gertner, MPH

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# The Board of Medicine's hospital resignation 'mouse trap'



By Andrew L. Hyams, Esq.

Any physician contemplating resignation from a position at a health care facility needs to be aware of a Massachusetts Board of Registration in Medicine "mouse trap" that can

place him or her in professional peril.

Some historical context is necessary to understand how this "mouse trap" works. For many decades, health care facilities have been required to report any "disciplinary action" against a physician to the Board of Medicine. In the mid-1980's, health regulators became aware of the unfortunate practice whereby a physician, accused of a serious offense by a hospital, would quietly resign and go to another hospital or another state, before the hospital reached a final disposition of the accusation.

First Massachusetts, and then the National Practitioner Data Bank, put a stop to this by requiring hospitals to report such resignations as "disciplinary actions." While intuitively we understand that the physician's act of resignation is not the equivalent of the hospital affirmatively taking a final disciplinary action, the profession and its lawyers came to understand that "disciplinary action," as a term of art, could include a resignation in the midst of unresolved and often serious accusations.

The source of the "mouse trap" is the Board's erroneous interpretation of the phrase "disciplinary action" as defined un-

der the Board's regulation, 253 CMR 3.02. Although this is not stated in the regulation itself, the Board interprets the term "disciplinary action" to include a resignation submitted while an investigation is pending, *even if the physician is unaware of the investigation*. This is an expansive interpretation

even if the physician is unaware of a pending investigation is inconsistent with the instructions the Board provides to health care facilities when they complete the required disciplinary action report form. Those instructions state: "The Board assumes that the facility has afforded the

procedural due process."

Indeed, the irony here is that it is the Board's interpretation that translates into the physician's complete loss of due process rights at the hospital. The physician resigns, unaware of a pending investigation, the Board labels the resignation a "disciplinary action," and then the physician is unable to claim a right to a due process hearing because he or she is no longer on staff at the hospital.

This particular type of "disciplinary action" throws the physician into a professional horror show. The Board reports publicly on its physician profile website that the hospital has "imposed discipline," even though the hospital, independent of the Board's interpretation, would say that it had not. The physician never got a hearing and cannot appeal at the hospital level.

Further, the Board launches a disciplinary investigation, which can go on for months or even years, and the physician is kept in the dark because, lacking the hospital hearing and being no longer on staff, the physician has no access to documents, medical records or witnesses. And with a disciplinary report posted on the website and a pending Board investigation, it can be impossible to find employment.

The Board's interpretation is inconsistent with its own regulation, which requires a "disciplinary action" resignation to be either "related to competence" or related to a bona fide complaint of a regulatory or bylaw violation. The Board's disciplinary action form

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that not only goes beyond the regulatory language, but also goes beyond the intent behind it, and at the same time sets up the unaware physician for harsh and surprising consequences.

A reported disciplinary action is posted as part of the physician's profile on its website, regardless of whether the Board actually investigates the initial allegations. Calling this type of resignation a "disciplinary ac-

physician procedural due process, when applicable, unless otherwise notified."

If a health care facility reports a disciplinary action based on an investigation the doctor didn't know about, then the doctor could not have received procedural due process, which would include notice of the allegation and the opportunity to respond. With no notice, there can be no due process. The Board is thus in no position to "assume that the facility has afforded the physician



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# Listening In

The news beat  
of the medical profession

## Mental health center institutes ban on smoking

Berkshire County's main lifeline for mental illness and substance abuse has declared all its campuses tobacco-free and begun tobacco cessation counseling, steps its medical director said are innovative in the state.

The Berkshire Eagle reported that the Brien Center in Pittsfield serves a demographic that smokes at more than three times the rate of the general population, according to medical director Dr. Jennifer Michaels.

"Tobacco companies touted the idea that people with mental illness smoke to self-medicate their emotional issues," Michaels said. "We recognize that that's all false; [tobacco addiction] is just another disease."

Michaels said the new ban and counseling are ahead of the state curve, noting that she gave a lecture in January in Eastern Massachusetts discussing the decision and other providers there laughed, citing the pervasive culture of smoking at their mental illness programs.

But Michaels said her plan is part of a new movement in the field to break from the attitude that mentally ill people shouldn't have high expectations for their wellness.

Michaels said that 75 percent of people with mental illness smoke – compared to 22 percent of the general population – and die on average 25 years earlier, largely because of preventable diseases that are commonly consequences of tobacco addiction.



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The policy, which would penalize physicians in 2012 if they don't e-prescribe in the first six months of 2011, will hurt efforts to implement widespread health IT adoption among physician practices and cause them to take on needless financial and administrative burdens, according to the AMA.

The Centers for Medicare and Medicaid Services has said that physicians cannot receive incentives from both the Medicare e-prescribing incentive program and the Medicare EHR incentive program simultaneously; however, if physicians choose not to participate in the 2011 e-prescribing program, they will face penalties in 2012 and 2013.

"This unreasonable policy leaves many physicians with little choice but to purchase and use a stand-alone e-prescribing program during the initial months of 2011 just to avoid penalties," said AMA Board Secretary Steven J. Stack, M.D. "HHS must take action now to align the e-prescribing and EHR incentive programs in order to alleviate confusion and reduce financial and administrative burdens on physician practices working to adopt health IT."

## 'Defensive' imaging common, costly

Over one-third of the cost of total diagnostic imaging generated by orthopedic surgeons may go to tests performed to avoid the risk of litigation, according to a study by the American Academy of Orthopaedic Surgeons.

Members of the Pennsylvania Orthopaedic Society were asked to voluntarily and anonymously record a consecutive series of patient imaging decisions in various settings. For the 72 physicians who responded, 396 tests (19 percent) were ordered for defensive purposes and defensive medicine accounted for \$113,369 (34.8 percent) of the total spending for tests included in the study.

The researchers noted that this is the first study to "prospectively collect data on the cost and prevalence of defensive medicine in any specialty of medicine" and concluded that the practice was "both common and costly."

## Study: PCP-specialist communication lagging

Communication between primary care physicians and specialists regarding referrals and consultations is often inadequate and could be improved by focusing on matters as basic as time spent with patients and nurse support, according to a new study published in the Archives of Internal Medicine.

The study conducted by Ann S. O'Malley, M.D., and James D. Reschovsky, Ph.D., found that 69.3 percent of PCPs reported "always" or "most of the time" sending notification of a patient's history and reason for consultation to specialists, but only 34.8 percent of specialists said they "always" or "most of the time" received such notification.

Similarly, 80.6 percent of specialists said they "always" or "most of the time" send consultation results to the referring PCP, but only 62.2 percent of PCPs said they received the information. Physicians who did not receive timely communication regarding referrals and consultations were more likely

to report that their ability to provide high-quality care was threatened.

The three practice characteristics associated with PCPs and specialists who reported stronger communication regarding referrals and consultations were "adequate" visit time with patients, receipt of quality reports regarding patients with chronic conditions and nurse support for monitoring patients with chronic conditions.

## M.D. groups: Revise e-Rx penalty policy

The American Medical Association and 103 state and specialty medical societies have urged the Department of Health and Human Services to revise the Medicare e-prescribing penalty policy in a letter sent to HHS Secretary Kathleen Sebelius.

## Doctors missing strokes in children with anemia

Doctors may be missing "silent strokes" in a small but significant number of children

## Rare cancer linked to saline, silicone breast implants

The Food and Drug Administration has announced a possible link between saline and silicone breast implants and a rare type of cancer.

Data reviewed by the agency indicated that people with breast implants have a small but significant increased risk of anaplastic large cell lymphoma (ALCL) in scar tissue adjacent to the implants.

The FDA is now working with manufacturers of the im-

plants to update their product labeling to reflect the newly found association, and the agency is also asking health care professionals to report any cases of the disease in women with breast implants.

"We are working with the American Society of Plastic Surgeons and other experts in the field to establish a breast implant patient registry, which should help us better understand the development of ALCL in women with

breast implants," said Dr. William Maisel, chief scientist and deputy director for science in the FDA's Center for Devices and Radiological Health.

The FDA noted about 60 cases of ALCL in women with breast implants worldwide, although agency officials said the number is difficult to verify. An estimated 5 million to 10 million women worldwide have breast implants.

The FDA also plans to provide an update on its review of silicone gel-filled breast implants, including interim findings from ongoing post-approval studies for silicone gel-filled breast implants currently sold in the United States, in the spring of 2011.

— Kimberly Atkins



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with severe anemia, who may be unfairly labeled as slow learners when in fact they have a medical problem, new research suggests.

Strokes have long been known to be a risk for kids with sickle cell anemia, and a new study has found that strokes are even more common than once believed in these children.

In addition, the study found that strokes also are occurring undetected in children who do not have sickle cell but have other conditions that can cause anemia, such as

cancer, kidney failure or blood loss from trauma such as a car crash. Some of the children had what researchers described as the brains of 80-year-olds when they were only 5 or 10.

The study involved only 52 children at Children's Medical Center Dallas, but experts believe the findings have wide relevance. One percent of all admissions to the hospital, or about 400 children over two-and-a-half years, were for severe anemia, said pediatric neurologist and study leader Dr. Michael Dowling.

## Report finds many U.S. kids lack docs

Though there are enough children's doctors in the United States, they work in the wrong places, a new study has found.

Almost 1 million children live in areas with no local doctor. By relocating physicians, nearly every child could have one nearby, according to the study, which appeared in the journal *Pediatrics*.

The study's lead author, Dr. Scott Shipman

of the Dartmouth Institute for Health Policy and Clinical Practice, said the increase in the number of pediatricians and family physicians has outpaced the child population growth, but the result has been more doctors in places where there is already an oversupply. The focus, he said, should be on evening out the distribution of physicians.

Federal financing has been expanded in recent years for the National Health Service Corps, which offers loan forgiveness for doctors and other health practitioners who work in underserved areas.

## Diabetes drug warning label changed

The type 2 diabetes drug Avandia, the subject of thousands of lawsuits, will get a new warning label and medication guide, according to manufacturer GlaxoSmithKline.

The new label will provide information about tighter Food and Drug Administration restrictions on the drug and warn of potential heart failure linked to the drug.

Approximately 13,000 lawsuits claim the company failed to warn about the risks of heart attack, heart failure and strokes. The company recently settled several lawsuits on the eve of trial, but has yet to make a global settlement of the claims.

According to a company press release, the revised labels restrict Avandia to patients already taking medications containing rosiglitazone and to new patients who are unable to control their diabetes with other medications or who, in consultation with their doctor, have decided not to take alternatives for medical reasons.

In September, the FDA required GlaxoSmithKline to establish a program to restrict the availability of Avandia. The company is still working to finalize a program, according to its press release.

— Sylvia Hsieh



AP Photo/Paul Sakuma, file

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# Bills, Rules & Regs



## From Beacon Hill

### Officials push for new youth concussion regs

State health authorities have proposed stringent regulations aimed at reducing head injuries in adolescent athletes and assuring that injured players don't return to the field until they have recovered.

The Boston Globe reported that the rules give form to emergency legislation enacted last summer amid burgeoning concerns about the long-term consequences of concussions.

The rules would require parents and students in middle school and high school to complete online training courses annually. Schools would have to maintain records on head injuries and doctors would have to undergo additional training.

Officials presented the regulations to the Public Health Council, whose blessing is required for passage. A vote is expected in late spring.

The concussion rules would apply to public schools as well as to private schools that belong to the Massachusetts Interscholastic Athletic Association. That organization, as well as the Massachusetts Association of School Committees, expressed general support but cautioned that record-keeping requirements could prove onerous for administrators already grappling with new rules governing bullying.

Massachusetts is one of nine states that have adopted laws designed to protect student athletes from concussions and the potentially lethal complications that can ensue from repeated head injuries, according to The Globe.

### State employees must enroll in health plans

The state Group Insurance Commission has voted to require all state employees to re-enroll in health care plans, the Patrick administration has announced.

The GIC promised a three-month "premium holiday" for those who choose lower cost, limited network plans, according to the announcement from the state Executive Office of Administration and Finance.

The plan will be offered in this spring's annual enrollment and go into effect July 1.

According to the administration, employees who move to the lower cost plan next fiscal year will save an estimated \$800 for an individual and \$1,700 for a family plan.

The GIC intends to negotiate lower rates and provide an incentive to employees to

join limited network plans, which state officials say "have essentially the same benefits as the more expensive health plans, with fewer providers."

"People can still have freedom of choice—they can decide to move to a lower cost plan, or stay with a higher priced broad network plan, but they do have to make a formal choice," said Dolores Mitchell, executive director of the GIC.

Administration and Finance Secretary Jay Gonzalez said, "Employees could save over \$1,000, between the lower premiums and the incentive, and the Commonwealth will save tens of millions of dollars."

### Mass. sets record for Medicaid recovery

Attorney General Martha Coakley's office has announced that its Medicaid fraud division recovered \$66 million for the state in 2010, nearly \$15 million more than the previous annual high, set in 2009.

The division took an active role in securing several lucrative settlements stemming from multi-state agreements with pharmaceutical companies, including an \$18.8 million payment from AstraZeneca as part of a national settlement to resolve allegations that the company fraudulently marketed one of its anti-psychotic drugs for off-label uses.

Since Coakley became attorney general in 2007, the number of investigators and attorneys assigned to the unit has risen by more than 50 percent, while the division's budget has climbed by more than 30 percent over the same time, according to Coakley's office.

### Towns opt to borrow to cover health costs

In the most recent example of Massachusetts municipalities turning to credit cards and Beacon Hill for short-term help with health care costs, state legislators have passed a bill that would permit another town to borrow \$445,000 to cover health care claims.

According to Rep. Christopher J. Donelan, a Democrat who represents the town of Orange in the House, his town used to be self-insured but voted in April 2010 to shift to private insurance coverage. After the switch, unpaid claims from the town's self-insured days continued to pour in, leaving the town \$445,000 in the hole and exhausting the local health insurance trust fund intended to cover cost overruns.

Richard Kwiatkowski, town administrator, said that the high cost of health care and inaction on controlling municipal health costs on Beacon Hill had led to the town's predicament and its effort to borrow.

Kwiatkowski pointed out that other cities and towns have faced similar – and in some cases, greater – challenges in covering health care costs. Orange modeled its borrowing plan on one approved in July 2010 for North Adams, said Donelan, who added that a handful of other communities have also sought such authority. The North Adams plan let the city of about 15,000 borrow \$880,000 for health bills.



## From Capitol Hill

### U.S. approves \$157M for local hospitals

Massachusetts will receive \$157 million in federal funds that will help trigger the release of \$230 million in payments to hospitals that serve a disproportionate share of low-income and uninsured patients.

The funds are expected to provide state matches and free up the flow of funding to Boston Medical Center and hospitals in Brockton, Dorchester, Lawrence, Holyoke and Springfield.

Cambridge Health Alliance has already received about half of the \$486 million in funds approved last October by federal government health care administrators.

The payments stem from the state's application last March for amendments to its Medicaid waiver with the federal government. The new waiver agreement gives the state the authority to make \$230 million in payments to Boston Medical Center, Brockton Hospital, Caritas Carney Hospital, Holyoke Medical Center, Lawrence General Hospital and Mercy Medical Center.

The payments will be made in two installments and will be distributed based on each institution's percentage of state-supported care, relative to their percentage of privately insured patients.

### FDA changes medical device review process

In a move it said will encourage innovation while protecting patient safety and increasing transparency, the Food and Drug Administration announced changes to its process of reviewing certain medical devices before they go to market.

The FDA announced 25 actions it intends to implement this year, including streamlining the "de novo" review process for certain innovative, lower-risk medical devices; issuing guidance clarifying when clinical data should be submitted in a premarket submission; and establishing a new Center Science Council of senior FDA experts to ensure timely and consistent science-based decision making.

The moves will create "a smarter medical device program that supports innovation, keeps jobs here at home and brings important, safe and effective technologies to patients quickly," said Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health.

The changes reflect some of the 55 recommendations made by two internal working groups set up by the agency to address concerns related to the premarket notifica-

tion process. The groups found that the process for premarket review of lower-risk medical products such as certain catheters or diagnostic imaging devices – known as 501(k) – was unpredictable, inconsistent and opaque. Consumers and health care professionals commented that the review process wasn't robust enough.

The Center has also asked the independent, nonprofit Institute of Medicine to study the 501(k) review program. That review is still under way.

– Kimberly Atkins

### Mass. misses out on insurance bonuses

Although 15 states won a combined \$206 million from the federal government for efforts to enroll children in health insurance, Massachusetts – whose leaders recently boasted a 99 percent rate of insured children – was not among the winners.

Cindy Mann, deputy administrator of the federal Centers for Medicare and Medicaid Services, said awardees were chosen based on improvement in children's enrollment in Medicaid since the enactment of a 2009 law reauthorizing Children's Health Insurance Program (CHIP) programs.

Because Massachusetts and several other states already had substantial child enrollment in health insurance prior to that law, Mann said, it would have been "pretty much impossible for them to qualify."

Alabama won the greatest share, \$55 million, for its efforts to simplify enrollment procedures for children in Medicaid and CHIP.

### FTC releases medical identity theft guide

The Federal Trade Commission has released information for health care providers and health insurers about how to help patients minimize the risk of medical identity theft and deal with the consequences if it occurs.

"The Medical Identity Theft FAQs for Health Care Providers and Health Plans" says that indications that medical identity theft has occurred include health plan statements showing that benefit limits have been reached and insurance claim denials based on medical conditions the patient doesn't have.

Health care providers and insurers should advise victims to notify health plans, file complaints with police and the FTC and review credit reports, the report states.

### Budget delays cuts for doctors again

A proposed 25-percent cut to physicians' Medicare payment rates will be delayed until the end of 2013 under a \$3.73 trillion budget sent to Congress by President Barack Obama.

In December, U.S. representatives followed their Senate colleagues by approving an 11th-hour, one-month delay of a cut to the rates, granting the current payment schedule a temporary stay.

Medical groups warn that as many as two-thirds of doctors could refuse to take on new Medicare patients if and when the cuts go into effect.

Critics point out that Obama's plan fails to specify how it will pay for the two-year delay in the Medicare payment cuts and that the budget also makes assumptions about economic growth that are more optimistic than those offered by many private economists.

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# Texas radiologist wins \$482 million patent verdict

By Kimberly Atkins

A Texas jury has awarded \$482 million to a radiologist on his claim that a medical stent manufacturer willfully infringed his patent.

It took only two hours for the jury to deliberate and then find that Cordis Corp., a subsidiary of Johnson & Johnson, willfully infringed on the patent developed by Philadelphia radiologist Dr. Bruce N. Saffran.

Paul R. Taskier, trial attorney for Saffran, said the key to winning was having witnesses and co-counsel who could present the highly technical facts of the case in a way that the jury could easily understand.

"We had extraordinarily good witnesses, including two technological experts and one damages expert who were fantastic, and we had our client, who was a terrific witness as well," said Taskier, a partner in the Washington office of Dickstein Shapiro.

### 'My gosh, that looks like my patent!'

Saffran claimed that in 1996 he developed a patent for the "Method and Apparatus for Managing Macromolecular Distribution," a technological process to be used in medical devices such as stents.

He then contacted several companies, including Cordis, to inquire if they had any interest in working with him to develop medical devices using the process. They declined, according to Taskier.

In 2001, while doing research, Saffran discovered that Cordis was conducting trials for its newly developed product, the Cypher drug-eluting cardiac stent. When he evaluated the product more, he found something that looked familiar, Taskier said.

"He said, 'My gosh, that looks like my patent!'" Taskier said.

Saffran contacted the company, which denied using his patent.

He filed suit in U.S. District Court for the Eastern District of Texas, which frequently hears patent claims, alleging willful patent infringement.

In a separate, related case, Saffran won a \$501 million verdict against Boston Scientific Corp. over the same patent in 2008. That case ultimately settled for \$50 million while the appeal was pending.

"I was surprised that the second case went to trial," Taskier said, adding that Cordis never made a settlement offer.

### Experts key

Taskier said that the plaintiff was prepared with a witness list of the nation's top experts to testify.

"[Our experts] demonstrated a command of all the materials and theories, and that was a key driver in convincing the jury, particularly because the experts relied on Johnson & Johnson's own documents and the testimony from their witnesses," Taskier said. "Utilizing the other side's documents and witnesses was very compelling to the jury."

Calls to attorneys for the defense were directed to Cordis. In a statement, Cordis spokeswoman Sandy Pound said that the company was "disappointed with the jury's ruling."

"The company believes this is contrary to both the law and the facts set forward in the case. We will ask the judge to overturn this verdict and if unsuccessful, we plan to appeal," Pound said.

Saffran has a third case pending against Abbott Laboratories over the same invention. That case is scheduled to go to trial in August 2012.

MMLR

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



Dr. Bruce Saffran, a Philadelphia radiologist, won \$482 million after a jury found that a Johnson & Johnson subsidiary willfully infringed on his patent for a medical device process used in stents.

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# Jury awards \$10.7M against 'pill mill' for patient's death

By Correy E. Stephenson

A Texas jury has awarded almost \$11 million to the family of a man who died after being prescribed a deadly cocktail of drugs from a local "pill mill."

The verdict is believed to be the first civil verdict in the country against a "pill mill," said Tommy Hastings of The Hastings Law Firm in The Woodlands, Texas, who represented the patient's family.

He said the Drug Enforcement Agency has declared Houston one of the worst places for "pill mills," pain management clinics that sell narcotics without a legitimate medical need.

Michael Skorpenske died three days after he received a prescription for a lethal combination of drugs the first and only time he visited the Family Medi Clinic in The Woodlands. Skorpenske's family filed suit against the clinic, its director and owners.

After a three-day trial and one full day of deliberations, a 12-person jury awarded a total of \$10.7 million against the defendants, \$8 million of which was punitive damages.

"Our biggest obstacle was getting past the natural prejudice that potential jurors would have about people who overdose on medicine," Hastings explained. Jurors might have held Skorpenske responsible because he put the drugs in his body, but "ultimately, we were able to prove that he had zero fault in this."

Greg Heath, a Houston attorney at Heath & Associates and a lawyer for one of the co-owners of the medical clinic, said of the verdict, "It is what it is. It didn't go the way I thought that it should."

Thomas Swanson, a sole practitioner in Houston, and Don Lewis, of Houston-based Lewis & Associates, who represented other defendants in the case, did not respond to calls requesting comment.

## A 'death sentence' prescription

According to Hastings, Skorpenske typically went to the VA hospital to get pain medicine for a recurring back injury. But he was having seizures and wasn't supposed to be driving, Hastings said, which was a problem because he lived more than 40 miles from the VA.

So Skorpenske went to the Family Medi Clinic, which he had seen advertised not far from where he lived. He was prescribed three drugs: Vicodin, Xanax and Soma.

The combination of drugs "is typically given to addicts," Hastings explained, and was particularly lethal for Skorpenske because of several pre-existing medical conditions, including liver problems, COPD (chronic obstructive pulmonary disease) and apnea.

The Xanax prescription alone was "eight



Michael Skorpenske, pictured with his daughters, died three days after receiving a prescription for a lethal combination of drugs from a Texas pill mill. Attorney Tommy Hastings, right, won a \$10.7 million verdict on behalf of Skorpenske's family.



times what would normally be given to a first-time patient," Hastings said, and the Vicodin was twice the dose Skorpenske usually took. Just three days later, Skorpenske died of an overdose, and his surviving family – his 86-year-old mother, two adult children and a 15-year-old daughter – filed suit.

At trial, the clinic's medical director, Dr. Maurice S. Conte, repeatedly took the Fifth Amendment during his testimony, Hastings said.

"His lawyer told the jury that pain management is controversial," he said. Dr. Conte, a 72-year-old general practitioner, was also the medical director of 16 other clinics in the area, Hastings noted.

Hastings said that Dr. Conte, who surrendered his medical license days after Skorpenske's death, never set foot in the clinic. It appears likely that the clinic used a pre-signed prescription form to prescribe the drugs to Skorpenske, Hastings said, but that's unclear because the clinic destroyed many of its medical records.

The clinic itself was a defendant, as were co-owners Melissa Martin, a part-time medical assistant, and Michael Kabizinski, a chiro-

practor. (Kabizinski settled before trial. Martin's husband, Lewis Martin, a Harris County Sheriff's Deputy, was also a co-owner, but the plaintiff didn't discover his involvement until after the statute of limitations had run.)

The final defendant was Jimmy Moore, a recruiter hired by the clinic to find a medical director. Moore testified that "he had no obligation to do any background checks" on the doctors he placed, Hastings said. "He said his job was to put A with B."

Hastings presented expert testimony that there was no legitimate medical reason to prescribe the three medications in combination, and educated the jury about the difference between a pill mill and a legitimate medical clinic. His expert also testified about Skorpenske's medical conditions and why the cocktail of drugs he was prescribed "was a death sentence for this man," Hastings said.

Family members testified, including Skorpenske's now 88-year-old mother and his teenage daughter, who was two weeks from her 16th birthday when her father died, Hastings said. Her testimony was "very emotional," he said.

## Deliberation and damages

After a day of deliberations, the jury awarded Skorpenske's family \$1.7 million in compensatory damages and \$8 million in punitive damages against Dr. Conte.

Jurors also awarded \$1 million in punitive damages against the clinic and approximately \$85,000 against Moore.

Hastings, who spoke to one of the jurors after the trial, said deliberations lasted an entire day because of the very long jury charge and a lone holdout in the verdict against Moore, the recruiter. Texas requires a jury to vote 10 to 2 or 11 to 1 for a liability verdict, but be unanimous for a finding of punitive damages, he explained. While 11 jurors wanted to award punitives against Moore, a lone juror refused.

But Hastings, who asked the jury for \$20 million in damages, said he was pleased with the result.

"The jury was trying to send a message to other pill mills," he said. **MMLR**

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

# The Board of Medicine's hospital resignation 'mouse trap'

Continued from page 3

states: "In addition, the Board interprets 'related to competence' as including situations in which a physician withdraws an application or agrees to the imposition of a disciplinary action while the facility is conducting an investigation, even when the facility does not make a final determination on the subject(s) of the investigation."

If the physician is unaware of the investigation, it is impossible for the physician to "agree to the imposition of a disciplinary action," and thus under this Board instruction, the resignation cannot be "related to competence." Yet, the Board ignores its own form and insists that the physician who resigned while unaware of an investigation must be reported to the public as disciplined by his or her former hospital.

I was general counsel at the Board from

1985-1990. As the attorney who drafted the definition of "disciplinary action" under 253 CMR 3.02, I can state unequivocally that the current Board's interpretation of the regulation is at odds with the Board's intent at the time the regulation was promulgated. The Board's purpose then was to shut down the unfortunate practice of allowing an incompetent or unethical physician to submit a "quiet resignation," only to pop up at another unaware hospital. The purpose was not to set a "mouse trap" for the unsuspecting physician, as the current Board has done.

Unless a court overrules the Board, any physician contemplating resignation from a health care facility should take the following precautionary steps:

1. When contemplating a resignation, affirmatively inquire as to whether there are

any pending complaints against you or whether your professional conduct is subject to any investigation. If there is anything pending, seek legal advice from an attorney well-versed in hospital reporting requirements before resigning.

2. Regardless of whether a complaint or investigation is pending, include in your resignation a "due process reserve" clause. Individual legal situations are unique and you should rely on your own attorney for legal advice. I have recommended to physicians that they include something along the following lines: "This resignation is void if, at the time it shall otherwise be effective, there is any pending complaint or investigation regarding me (regardless of whether I am aware of such complaint or investigation) which might result in the health care facility

filing a disciplinary action report at the Board of Registration in Medicine. For avoidance of doubt, this resignation is void if it limits my due process rights to answer and otherwise resolve a pending complaint or investigation."

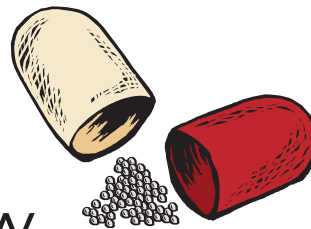
It is regrettable that the simple act of resignation forces a physician first to run to a lawyer for advice, but until the Board can be convinced that its interpretation of its regulation is erroneous, I see no alternative. **MMLR**

Andrew L. Hyams is a partner at the Wellesley law firm, Kerstein, Coren & Lichtenstein, LLP. He was general counsel at the Board of Medicine from 1985-1990, and he currently represents physicians and other health professionals in regulatory and peer review proceedings. He can be reached at [AHyams@kcl-law.com](mailto:AHyams@kcl-law.com).

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# Good Medicine



What doctors are talking about now

**Q:** A 1986 state law requires a patient's written informed consent for HIV testing and each release of test results. Is this law still necessary or would different statutory or regulatory requirements better serve patients, providers and the public health?

"Given the current status of the HIV/AIDS epidemic, changing attitudes about HIV and the dramatically improved prognosis for HIV-infected persons, it is appropriate to reassess policies and laws governing diagnostic tests for HIV infection. Treating diagnostic testing for HIV differently than for other infectious diseases makes little sense, and frequently interferes with optimal delivery of care for the person involved. I strongly support the view put forward in the CDC guidelines that testing for HIV should come under the general consent for medical care and not require separate, signed informed consent. Release of test results should be governed by the same laws that apply to the release of other protected health information."

— Daniel Kuritzkes, MD,  
Director of AIDS Research,  
Brigham and Women's Hospital

"The law is as relevant today as it was when it was first passed. Allowing HIV-positive patients to determine for themselves who knows their HIV status is something our state has long protected. Despite all of the medical and societal advances in our understanding of HIV/AIDS, stigma still exists, and people living with HIV still face discrimination. We can and should update the law to ensure that HIV testing is not burdened by an overly cumbersome process, but we must continue to protect the confidentiality of those being tested. Every legislative session there are proposals to force HIV-positive patients to disclose their status, so updating this law needs to be handled thoughtfully to prevent opening the door to other, less well-meaning proposals."

— Rep. Carl M. Sciortino Jr.,  
D-Medford

"In Massachusetts, we successfully reduced new diagnoses of HIV infection by 59 percent between 1998 and 2008. Further reductions require a change in existing state law. That's why we support 'An Act Promoting Routine HIV Screening in the Commonwealth.' The bill would replace the need for written consent from patients with verbal consent, with the physician noting in the patient's medical record whether the patient consented to be tested, while maintaining current privacy protections. Given that large numbers of those who have tested positive have not been effectively linked to care, the legislation also requires that those testing positive be connected to care. The proposed legislation integrates the lessons of the last 30 years and positions Massachusetts to make further inroads in reducing the infection rate."

— Denise McWilliams,  
general counsel,  
AIDS Action Committee

"At the time the law was passed, a strong stigma [about] the disease still existed. The law is an attempt to strike a balance between the serious public health concerns associated with HIV and the privacy concerns of the patient. Allowing for simple verbal consent takes away the documentation that provides protection to health care providers. If verbal consent were allowed and a patient challenged testing or the release of results, the courts would be without written evidence that could facilitate a sound decision as to whether consent was given. Given the serious implications of releasing such results, written informed consent is still the best protection for health care providers who could potentially face increased liability exposure if verbal consent were allowed."

— Stephen C. Pfaff,  
principal, Louison, Costello,  
Condon & Pfaff, Boston



## HIV testing best served by CDC approach, not state law

By Lynn Black, M.D., M.P.H.

In 1986, Massachusetts lawmakers enacted an HIV consent law (Chapter 111, Section 70F), stipulating that patients could not be tested for HIV without written, informed consent and that patients must give written, informed consent for each release of test results.

While the law offered protection from discrimination, unintended consequences resulted: it was harder to discover how widespread the disease was and how it was being transmitted.

Remember the time: HIV/AIDS was an emerg-

ing threat. Infections were soaring. Fears arose about casual transmission, and people losing their jobs and being refused medical treatment if their infection became known. Fear of discrimination added to the fear of infection.

Fast forward two decades. In September 2006, to curtail new infections, the Centers for Disease Control and Prevention revised its recommendations for HIV testing to advocate routine, voluntary HIV screening as a "normal part of medical practice, similar to screening for other treatable conditions." The CDC also said that "separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing."

However, at the same time, the CDC increased pressure on the states to adopt uniform reporting standards that would include patient names. Federal assistance for HIV patients was suddenly at stake. Two months later, the Massachusetts Department of Public Health, fearful of losing millions of dollars, adopted emergency regulations to mandate physician reporting of HIV-infected patients by name – regardless of consent.

The CDC's desire for name-based reporting was in conflict with the 1986 state law. Physicians' attempts to resolve the conflict failed, leaving them to make an awkward decision: adhere to the 1986 law or comply with the new 2006 emergency regulations?

DPH then issued a legal opinion, providing a defense for a physician who followed name-based reporting without the patient's written informed consent. (DPH currently collects named-based reports on some 30 diseases directly from physicians and more than 80 directly from labs, including a half-dozen STDs.)

The 1986 law still exists today and remains in conflict with CDC reporting and testing standards.

Now comes an "Act to Increase Routine

Screening for HIV," proposed legislation to replace Section 70F. While this Act contains some effective provisions – resolving one conflict with state law by legalizing name-based reporting and protecting providers from civil or criminal liability for reporting mandated information, including patient names – it presents more burdens than benefits.

This proposal would require "every health care provider who delivers primary medical care services or infectious disease services to an adolescent or adult patient" to offer HIV testing. Testing may be done with the "verbal informed consent of the patient," but providers must document the patient's acceptance or denial of consent in the medical record.

The proposal essentially mandates standards of care by statute: offering a test to patients not at high risk and giving authority to DPH to identify patients at a high risk of contracting HIV and to set the frequency with which providers shall offer testing. However, standards of care, for any medical condition, should be determined by sound clinical practice and evaluated by peer review and the Board of Registration in Medicine. Political advocacy to change clinical standards by law is common, but rarely appropriate. Standards of care should not be mandated by legislative acts.

The proposal also goes beyond current law, creating confidentiality for all "HIV-related medical information" – that is, any information that indicates the patient was the subject of a test, identifies a patient as having HIV or AIDS, or notes the use of medications that might indicate such an infection. A diagnosis of HIV or AIDS has never previously been subject to statutory protections beyond the federal privacy of HIPAA.

The bill maintains the requirement of a patient's written informed consent for each release of information. These provisions would impede communication among providers, often work-

ing in teams, by establishing barriers around important information, such as prescription data, and could prevent the inclusion of such information in medical records. Not sharing clinical information is not responsible patient care, and subjecting providers to financial penalties for doing so is bad public policy.

Today, decades after the onset of HIV/AIDS, we have a great understanding of the clinical factors affecting HIV patients. Infection isn't the death sentence it was once thought to be. Laws now protect HIV-infected people from housing and workplace discrimination. Public fears and discrimination have diminished.

In Massachusetts, the number of people known to be living with HIV/AIDS has increased 39 percent from 1999-2007, according to DPH. Due to excellent clinical work by health care providers and community support systems, HIV-positive individuals now live productive and active lives. Nationally, the CDC estimates that more than one million people are living with HIV, with new infections totaling more than 56,000 every year. Many are unaware they are infected.

We can still do better at early detection, to continue to improve the quality of life of individuals and to reduce the likelihood infections will spread.

Efforts to increase routine HIV screening should be encouraged, not by legislation dictating how providers will treat patients, but by simplifying existing laws. Treat this condition like other infectious diseases and safeguard the information as other health data is protected. No special status or laws governing testing for this disease should be enacted.

The value of the CDC's approach is clear. Medical issues remain in the hands of clinicians. With available routine testing, infected patients get treatment sooner, resulting in better outcomes. An individual's health and the public health are better served.

Lynn Black, M.D., M.P.H., is an internist and chair of the Massachusetts Medical Society's Committee on Public Health.



Doctor's Rx

# Verdicts & Settlements

## Midwife forgoes C-section despite fetal tachycardia

In September 2003, an expectant mother began treatment at a health clinic affiliated with a hospital. Her estimated delivery date was March 24, 2004. In November, she was noted to have oligohydramnios, a deficiency of amniotic fluid.

An ultrasound performed on Dec. 9 again documented decreased amniotic fluid. However, another ultrasound two weeks later reported a normal amount of fluid, with the baby estimated to be in the 35th percentile at a gestational age of 26 weeks and one day with an appropriate amount of interval growth.

On the due date, the patient arrived at the hospital with complaints of a headache. Her blood pressure was noted to be 140/90, so she was sent for an induction of labor for suspected gestational hypertension.

She was admitted and given cytotec gel at approximately 10:15 p.m. Early the following morning, she was started on Pitocin. The baseline fetal heart rate was 130 beats per minute. A rupture of membranes occurred at 7 a.m. with heavy meconium and scant amniotic fluid noted. Around 10 a.m., the fetal heart rate was noted to be in the 120s with accelerations but was described as “not formally reactive.” Later that afternoon, the FHR was noted to be in the 150s, still with accelerations.

A subsequent review of the actual fetal tracing revealed a persistent, 90-minute episode of fetal tachycardia from 7:53 to 9:23, during which the baby’s heart rate spiked to 180 bpm.

The baby was delivered at 1:20 a.m. on March 26 by the defendant nurse midwife. The baby was born severely depressed, with Apgar scores of 1, 5 & 7 at 10 minutes. The baby was noted to be limp and blue with a heart rate of 70. Copious thick meconium was seen below the cords and the placenta was meconium-stained. The record indicated no complications with delivery.

An MRI of the newborn’s brain revealed changes consistent with perinatal hypoxia and hypoxic injury. The baby was noted to have perinatal depression likely related to hypoxic events during labor.

A NICU progress note by the doctor on March 27 states that the girl was diagnosed with hypoxic ischemic encephalopathy, probably secondary to severe perinatal depression. EEG testing continued to remain abnormal. The child was discharged approximately one week after delivery after her seizures were brought under control.

The girl has been diagnosed with cerebral

## Man’s vision worsens after two LASIK surgeries

A 28-year-old Texas resident went to his ophthalmologist in Massachusetts for LASIK surgery on both eyes.

Unbeknownst to the patient, based on the condition of his corneas, he was not a suitable candidate for LASIK surgery. Despite signs of this pre-existing corneal condition, the ophthalmologist performed the surgery, which made the patient’s vision worse.

After the surgery, the man experienced problems with his vision and returned to his ophthalmologist approximately four years later. Based on the condition of his corneas, he was still not a LASIK surgery candidate; nevertheless, the ophthalmologist recommended corrective LASIK surgery, also referred to as an “enhancement.”

This surgery compounded the effect of the original surgery and made the patient’s vision even worse. He developed post-LASIK ectasia and faces a possible corneal transplant. He suffers from physical pain in his eyes and headaches, as well as visual disability, including diminished uncorrected visual acuity and visual distortion. He continues to work as a respiratory therapist as well as drive and read, but with limitations.



The patient alleged that the ophthalmologist was negligent in failing to recognize his corneal condition. He brought claims against the ophthalmologist and the doctor’s employer.

The case settled for \$525,000.

**Action:** Medical malpractice

**Injuries alleged:** Vision damage and disabilities

**Date:** November 2010

**Submitted by:** Jeffrey N. Catalano and Julie A. Schreiner-Oldham, Todd & Weld, Boston; Todd J. Krouner, Chappaqua, N.Y. (for the patient)

palsy. She has ongoing neurological problems, including developmental delays and seizures, and has been declared legally blind.

The case settled at mediation for \$2.5 million.

**Action:** Medical malpractice

**Injuries alleged:** Failure to perform Cesarean section resulting in neurological injuries to child

**Date:** November 2010

**Submitted by:** Gregg J. Pasquale, Ann Marie Maguire and Melissa A. White, Keches Law Group, Taunton (for the mother)

## Man’s condition misdiagnosed

On Jan. 5, 2003, a 25-year-old male experienced sudden, severe testicular pain while lying in bed. That night, he presented to the emergency department of a Boston-area hospital. The ER physician who performed the examination ordered a testicular ultrasound

for what the physician believed to be a hernia.

The radiologist who interpreted the ultrasound reported findings consistent with a hernia. The ER physician discharged the plaintiff with instructions to follow up with the surgical service for hernia repair.

Less than two days later, the plaintiff returned to the same emergency department with even more severe pain. He was initially thought to have an incarcerated hernia but an examination performed at that time revealed the spermatic cord could be palpated above the scrotum – a finding that seemingly contradicted the diagnosis.

During surgery, it was revealed that the man’s left testicle had twisted 720 degrees and was necrotic. The testicle could not be saved and had to be surgically removed.

A review conducted by the plaintiff’s radiology expert revealed that the testicular ultrasound performed on Jan. 5 demonstrated absent blood flow to the left testicle – a strong indication of torsion – yet no further testing

or intervention was ordered or performed by the attending ER physician.

A key development in the case was the deposition testimony of the defendant ER physician, who testified that he personally viewed “videotape” of the plaintiff’s testicular ultrasound shortly after the ultrasound was performed by the hospital’s radiology department.

A subsequent deposition of the hospital’s chief technology officer revealed that the hospital did not own or operate equipment which would have permitted the ultrasound to be recorded on tape – or any other media – at the time that the defendant claimed to have reviewed the “recorded” results.

Medical experts were prepared to testify that had surgery been performed on Jan. 5, the testicle likely would have been saved.

The defendants claimed that the patient did not present to the emergency department with a classic presentation of torsion. They also argued that the testicular torsion was ruled out by the ultrasound, which they main-

# Verdict & Settlement Reports

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

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

## Doctors operate without reviewing records; patient dies

The 40-year-old patient was born with Tetralogy of Fallot, or TOF, an anomaly consisting of four heart defects: narrowing of the pulmonary valve, an opening between the right and left ventricle, an anomaly of the aortic arch and an enlarged right ventricle. A patent foramen ovale, or PFO, an opening in the septum between the atria of the heart, was also found at birth and was documented in the patient's medical records shortly after birth.

The patient had undergone surgical correction of the TOF as a 6-year-old. The PFO was not surgically repaired. Although the PFO was documented in the medical records shortly after birth up to and after corrective surgery at age 6, reference was not made to the existence of the PFO thereafter.

In 2007, the patient was referred by a cardiologist to a cardiac surgeon for pulmonary valve replacement surgery. The cardiologist, surgeon and cardiac anesthesiologist failed to obtain and review the patient's medical records prior to the surgery and thus did not know about the existence of the uncorrected PFO.

The anesthesiologist contended that he pre-operatively examined the intra-atrial septum to identify atrial communications, if any, and found none.

When deposed, each doctor testified that he had relied on another to provide information concerning the existence of the PFO, which was clearly documented in her medical records.

The surgeon testified that open heart



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surgery performed on a patient with an untreated PFO can be life-threatening.

The patient suffered a massive air embolus during the surgery, resulting in anoxic brain injury and death. The sole significant finding at autopsy was her PFO.

The physicians denied liability and contended that their care was appropriate in all respects.

The parties settled the case for \$2.5 million.

**Action:** Medical malpractice

**Injuries alleged:** Wrongful death

**Date:** August 2010

**Submitted by:** Patrick T. Jones and Donna R. Corcoran; Cooley, Manion, Jones, Boston (for the patient's family)

tained revealed a hernia-like mass.

The case settled for \$550,000.

**Action:** Medical malpractice

**Injuries alleged:** Failure to diagnose and timely treat testicular torsion leading to loss of testicle

**Date:** October 2010

**Submitted by:** Eric J. Parker and Susan M. Bourque, Parker Scheer, Boston (for the patient)

## Diabetic boy dies of complications

A 9-year-old boy died on Jan. 19, 2003, from diabetes mellitus.

The day before his death, the boy's father called the pediatrician's office and reported to the nurse practitioner that the boy was lethargic, disoriented and had been ill for the last three days, with vomiting for two days. The boy did not have a fever, rash or diarrhea. He was drinking ginger ale and urinating.

The nurse diagnosed the boy over the phone with a viral infection. She offered a visit to the emergency room but did not insist that the boy be seen in the ER for further evaluation. The plan was to have the boy checked the next day if he had not improved.

The boy's father checked on his son in bed at 4 a.m. and noted his respiratory rate was increased. At 8:28 a.m., he discovered the boy was not breathing and called 911. EMS arrived on the scene less than five minutes later and began CPR. The boy was apneic and pulseless, and his pupils were fixed, unreactive and glassed over. He was ashen/cyanotic and non-diaphoretic, and his torso was cool to the touch. He had rigor in his jaw, preventing oral intubation.

Upon his arrival at the hospital, the boy's eyes were open, his pupils were fixed and dilated and his corneas were cloudy. He did not have any spontaneous respiratory or cardiac movement. Resuscitation efforts continued without success, and the boy was pronounced dead at 9:20 a.m. His laboratory work-up revealed a blood glucose level of 1165 (the normal range is 50 to 80) and a

potassium level of 7.1 (the normal range is 3.5 to 5.3).

The nurse was accused of negligence for failing to identify lethargy and disorientation as symptoms of a potentially life-threatening emergency and failing to instruct the boy's parents to take him immediately to the ER for evaluation and treatment.

She contended that her care and treatment complied with the applicable standard of care, and that nothing she did or failed to do caused or substantially contributed to the boy's death. She noted that the father had described a child that was getting better, who hadn't vomited that day, who was awake at the time of the call, who could be heard speaking in the background and who was urinating and taking fluids. She further contended that the boy's father failed to communicate changes in the boy's condition following the telephone call.

The case settled a few weeks before trial for \$1 million.

**Action:** Medical malpractice

**Injuries alleged:** Undiagnosed diabetes leading to death of 9-year-old boy

**Date:** September 2010

**Submitted by:** Andrew C. Meyer and William J. Thompson, Lubin & Meyer, Boston (for the patient's family)

## Nurse gives baby paralyzing agent

A baby was born prematurely at 24 weeks gestation and was subsequently cared for in the hospital's neonatal intensive care unit.

A NICU nurse administered to the child a massive overdose of pancuronium bromide, or Pavulon, a neuromuscular blocking agent (and one of three drugs used in lethal injections). Administration of the drug causes all of a patient's voluntary muscles to become completely paralyzed. In the NICU, the drug is used for facilitating mechanical ventilation. However, on the morning in question, there was no order for the child to receive the drug.

At the time, pancuronium bromide was stored in the NICU in an unlocked refrigerator without any security; therefore, contrary

to safe medication storage practices, the amount of the drug that the nurse accessed was untraceable. As a result of the overdose, the boy remained paralyzed for approximately 24 hours. The hospital conducted an investigation and determined that the drug had been given by the nurse without authorization. The nurse was terminated and referred to the Board of Registration in Nursing.

The hospital wrote a letter to the patient's parents assuring them that despite the lengthy period of paralysis, the boy would suffer no adverse consequences as a result of the overdose. He remained in the NICU for a total of four months.

By the time the child was 2 years old, it was apparent to his treating physicians that he was displaying signs and symptoms of kernicterus, a syndrome that prevented his physical development and caused cerebral palsy, hearing loss and decreased oral motor function. He required a G-tube and continuous oxygen therapy delivered through a tracheotomy.

The family's experts would have pointed out that the package insert for pancuronium bromide warns that excessive exposure to the drug can cause kernicterus, especially in preterm infants, and that the NICU nurse had previously demonstrated severe behavioral issues.

The parties agreed to mediate the case. The boy died after the first day of mediation and the case settled shortly thereafter for \$3 million.

**Action:** Medical malpractice

**Injuries alleged:** Kernicterus

**Date:** Dec. 27, 2010

**Submitted by:** Lisa G. Arrowood, Jed DeWick and Alexis D'Arcy, Todd & Weld, Boston (for the patient's family)

## Psychiatrist settles in child's overdose

A 4-year-old girl died after being over-medicated with a powerful psychotropic drug cocktail.

The mixture included Clonidine, a sedative; Depakote, a mood stabilizer; and Seroquel, an anti-psychotic drug. Clonidine and Depakote are not approved by the Food and

Drug Administration for use in children. The medical examiner's autopsy revealed that the girl's death was caused by intoxication.

The prescribing psychiatrist started medicating the girl at 28 months with anti-psychotic drugs for hyperactivity and bipolar disorder. Experts were expected to testify that a diagnosis of bipolar disorder is impossible at such an early age.

On multiple occasions over the course of two years, the doctor filled prescriptions for psychotropic drugs over the phone without seeing or evaluating the child, increasing the dosages of these drugs on several occasions, including in the months leading up to the child's death.

The plaintiffs alleged that the medications prescribed by the defendant had noticeable, negative impacts on the child that were neither recognized nor appreciated by the psychiatrist. In November 2006, approximately six weeks before the girl's death, a school nurse called the defendant to report that the child was often so tired when she came to school that she could barely walk up the stairs and that she could not participate in classroom activities. The nurse compared her to a "floppy doll."

The doctor responded that she would consider decreasing the amount of the child's drugs, but never lowered the dosage, continuing to prescribe the same levels of Clonidine until the day she died. The last order of 35 Clonidine pills was filled just six days before the child's death.

The girl's father was convicted of first-degree murder for giving his daughter a lethal overdose of the psychotropic drugs. Her mother was convicted of second-degree murder.

It was anticipated that the defendant and her experts would testify that the child's parents, not the defendant, were responsible for the child's death.

The parties settled the case for \$2.5 million.

**Action:** Medical malpractice

**Injuries alleged:** Improper prescribing of medication by psychiatrist leading to death of a 4-year-old girl

**Date:** Nov. 5, 2010

**Submitted by:** Andrew C. Meyer Jr. and Benjamin R. Novotny, Lubin & Meyer, Boston (for the patient's estate)

# Learn to steer clear of common medical mistakes

Continued from page 1

## 1 Failure to properly supervise nurse practitioners and physician assistants.

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

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

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

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

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

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

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

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

there's more of a team-based approach as opposed to a hierarchical approach."

## 2 Failure to properly document decisions in the record.

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

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

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

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

## 3 Failure to follow up on patients' diagnostic tests.

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

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

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

The main point here is to have some kind of system in place, whether electronic or sim-

ply an accordion file sorted by date, says Huben-Kearney.

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

## 4 Failure to deal properly with noncompliant patients.

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

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

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

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

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

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

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

## 5 Failure to properly manage chronic-pain patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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# New Congress sets sights on med-mal reform effort

Continued from page 1

ty and leave people at risk for more injuries from negligent care," said Gibson Vance, president of the American Association for Justice in Washington, in a statement. "This is the most perverse form of legislating imaginable."

## Focus in Washington

Even before the current session of Congress began, the issue of tort reform began gaining steam in Washington, in part due to a report released by a White House commission tasked with making deficit reduction recommendations.

The National Commission on Fiscal Responsibility and Reform, in its "Moment of Truth" proposal of ways to reduce the budget, suggested that Congress implement a number of med-mal reform measures. Among other things, those suggestions included imposing a one- to three-year statute of limitations on med-mal lawsuits, creating health courts and allowing "safe haven" rules for providers who follow best practices of care.

"Many members of the Commission also believe that we should impose statutory caps on punitive and non-economic damages, and we recommend that Congress consider this approach and evaluate its impact," states the report by the 18-member bipartisan commi-

sion, released in December.

Such measures would save Medicare and other federal programs \$2 billion in 2015, and \$17 billion through 2020, according to the report.

Then in January, the Help Efficient, Accessible, Low-cost, Timely Health Care Act, or HEALTH Act, H.R. 5, was introduced in the House. That measure would cap noneconomic med-mal damages at \$250,000 and limit punitive damages to \$250,000 or two times the amount of economic damages awarded, whichever is greater.

It would also prohibit juries from being informed of liability limits before deliberations, cut attorney fees and shorten the statute of limitations for med-mal claims.

"[The bill's] proven reforms will make medical malpractice insurance affordable again, encourage health care practitioners to maintain their practices, reduce health care costs for patients and save billions of dollars a year in federal taxpayer dollars by reducing the need for 'defensive medicine,'" said Rep. Phil Gingrey, R-Ga., a co-sponsor of the measure.

Lawmakers urged Obama to support the bill. A day later, during his State of the Union address, Obama said he was open to considering some measure to curb the cost of meritless malpractice claims.

"I'm willing to look at other ideas to bring down costs, including one that Republicans

suggested last year: medical malpractice reform to rein in frivolous lawsuits," Obama said.

He did not detail what type of medical liability reform measures he might support. But his comments were broader than in his message last year, when he indicated a willingness to consider state-based medical malpractice reform measures, and several relevant provisions are included in his proposed 2012 budget. Last year, he went on to include a \$25 million grant program providing federal funding for state-based med-mal reform test projects as part of the health care reform law.

## 'Tort as last resort'

Woodward said one such pilot project funded by that program, an approach used by the University of Michigan Health System, would lower health care costs while speeding the process for injured patients to receive compensation for medical mistakes.

Under that approach, injured patients would receive full disclosure from physicians as to the reasons behind a medical injury. If an injury were avoidable, and not an adverse outcome without fault, the patient would be given an apology.

Then systems would be put into place to prevent the same error from happening in the future, and the patient would be offered com-

penensation. If the patient rejected the offer, the matter would go to mediation and then the patient would have the right to seek a civil action.

"If you ask patients, that is exactly what they want us to do," Woodward said. "We want to establish a baseline culture in every enterprise that allows patients to be fairly compensated quickly, while allowing doctors to learn from negative events."

The main benefit of that method is taking the compensation process out of the courts, Woodward said.

"We don't want tort reform. We want to take [compensation of injured patients] out of the tort system," Woodward said. "We want tort as a last resort."

Woodward said while "micro-reforms" such as liability caps have been shown to cut insurance premium costs, they don't stop lawsuits. The litigation-focused liability system makes patients wait too long for compensation – 5.5 years on average, Woodward said. And that is only counting those who see any compensation at all.

"When you get to the courtroom, physicians win 90 percent of the time," Woodward said. **MMLR**

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

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This course is intended for physicians and allied health professionals.

### Course Objectives

- Provide physicians and other practitioners with an understanding of the genesis of Accountable Care Organizations (ACOs).
- Describe the proposed models of ACOs under The Patient Protection and Affordable Care Act of 2010.
- Cite some potential medical-legal issues that physicians may face with the proliferation of ACOs.

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### Bibliography – see page 14

## A Primer on Accountable Care Organizations



By Craig Schneider, Ph.D.

The Patient Protection and Affordable Care Act of 2010 includes provisions to create “accountable

care organizations” (ACOs).

ACOs are health care providers that would be paid based on performance rather than purely on a fee-for-service basis. In Massachusetts, policy makers are looking to the ACO model as a way to reduce costs and improve quality. However, there is much that is unclear about what ACOs are and how they would work.

The Centers for Medicare & Medicaid Services (CMS) defines an ACO as “an organization of health care providers that agrees to be accountable for the quality, cost and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it.”

Conceptually, ACOs have three essential aspects:

- 1) The ability to deliver services across the continuum of care,
- 2) Prospective budgets, which establish the ACO’s total costs in advance, and
- 3) A sufficient number of patients to support the validity of performance measurement.

Elliot Fisher, MD, director of The Center for Health Policy Research at Dartmouth Medical School, who is credited with coining the term “accountable care organization,” has said that the three key attributes are organized care, performance measurement and payment reform. These attributes should be aligned to support physicians in improving the quality of care.

The theory behind ACOs is that, by taking on the risk of delivering care on a prospective payment basis, providers would have incentives to manage patient care across multiple settings. While this might sound like capitation revisited, the difference between the ACO (and other global payment models) and the managed care of the 1990s is the connection to quality measures. The incentives are based on delivering value, rather than on under-utilization (capitation) or over-utilization (fee-for-service) of health care services.

From the physician perspective, the orientation toward ACOs would require a major cultural shift, said Dr. Lawrence Casalino of Cornell Medical School to a *New England Journal of Medicine* roundtable. “Quality” will change from what the doctor does for an individual patient at the point of care to what the organization does for the population of patients throughout the year.

There are three different models of ACOs that are relevant to consider: a “virtual” organization that aligns physician practices, a hospital and perhaps other providers to receive value-based payments; an actual organization that integrates both the insurance and care delivery functions; and a legally



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contracted organization that is paid on a fee-for-service basis but shares savings for efficient quality care – the model that is used under the new Medicare program.

### • The virtual ACO

Under the virtual model, hospitals, physicians and other providers do not need to be legally organized, but might have a memorandum of understanding about how payments will be distributed.

For example, the PROMETHEUS payment model is designed to pay providers based on evidence-informed case rates for a specific condition, and allows either such “virtual” organizations or integrated delivery systems to participate. (See [www.hci3.org](http://www.hci3.org) for more information.)

### • The integrated ACO

While ACOs may seem like a theoretical construct, there are several prominent organizations that are serving this function today, and deriving their incentives for efficient and quality care by integrating the insurance and delivery roles.

Examples include Geisinger in Pennsylvania, Kaiser Permanente in California and other states, Group Health Cooperative of Puget Sound in Washington and Dean Health System in Wisconsin.

### • The Medicare ACO

The new Medicare program is scheduled to begin in January 2012. It is important to note that it is not a pilot or demonstration, but rather a permanent part of Medicare.

Each Medicare ACO must have a formal legal structure to receive shared savings payments and distribute them among participating providers, and must meet quality and reporting standards.

In addition, an entity applying to become an ACO must have at least 5,000 Medicare beneficiaries to ensure the statistical validity of performance measures. The organization must also have a defined process to promote evidence-based medicine, report data for quality and cost measures and coordinate care.

The Medicare ACO requirements include automatic assignment of patients to the ACO, per-

formance measurement, shared savings based on reducing costs relative to targets and no risk initially of provider costs exceeding budgeted amounts (although this could change over time).

Although patients are assigned to an ACO, Medicare beneficiaries served by the ACO would also be able to receive care outside of the ACO.

Medicare ACOs will have three-year contracts. Payment will be made on a fee-for-service basis, but the ACO will receive shared savings payments if spending is lower than the per-person spending growth for all Medicare beneficiaries in that ACO, with some complicated adjustments.

Further, bonus payments will be available for meeting quality metrics.

In addition to Medicare ACOs, the law allows states to establish ACOs for their Medicaid programs under a demonstration program beginning in 2012 that is designed for pediatric providers.

At the end of 2010, CMS sought comments on how small physician practices might participate (and suggestions for other payment models that might be appropriate for small practices), how to determine which beneficiaries are part of an ACO’s patient pool at a given time, how to measure patients’ care experience, quality metrics, measures of patient-centeredness and proposals for alternative payment methods.

Clearly, there are numerous details that still need to be determined.

In the interim, analysts are assessing the potential transformative impact of ACOs. Because the Medicare ACO program model does not involve risk and would pay providers based on fee-for-service rates, some have questioned how “accountable” these organizations have to be.

While some are dubious about the ability of ACOs to solve the problems with the health care system, there is widespread consensus that the fee-for-service system is broken, and Congress and CMS believe that the new Medicare program is a promising way to begin to transform it. **MMLR**

*Craig Schneider is the Director of Healthcare Policy at the Massachusetts Health Data Consortium in Waltham. The Consortium’s website is [www.mahealthdata.org](http://www.mahealthdata.org).*

## The Physician's Corner

# Thoughts on Accountable Care Organizations

By Henry Tulgan, M.D. FACP

Many physicians first became aware of the term "Accountable Care Organization" (ACO) when President Barack Obama signed the Patient Protection and Affordable Care Act into law on March 30, 2010. In fact, the concept in large measure derived from the Dartmouth Atlas Project, which has been in existence for over 20 years. The Project is an ongoing effort that uses Medicare data to study how medical resources are used across the United States. It documents variations and inequities in both quality and cost of health care which have thus far been inadequately addressed.

The specific term ACO appears to have been first introduced in a conversation between Elliott S. Fisher, M.D., M.P.H., Dartmouth Atlas Co-Principal Investigator, and Dr. Glenn Hackbarth in November 2006 at a Medicare Payment Advisory Commission (MedPAC) meeting.

ACOs are meant to be organizations that coordinate care within a global budget. They are developed by health care providers who then provide care to patients either through capitation or fee for service within a budget. What distinguishes ACOs from the failed capitation experiments of the past is the additional emphasis on quality, appropriate level of care and efficiency, and how these will influence reimbursement.

Some project that ACOs will save Medicare up to \$5 billion in the next seven years. Few of us may be aware of a recently completed pilot program sponsored by the Centers for Medicare and Medicaid Services involving 10 large integrated delivery systems to evaluate whether care management initiatives might generate Medicare savings.

Over five years, this exercise revealed that more refinement is needed to address potential financial and legal risks, including IT implementa-

tion and maintenance, and that a practice and behavioral shift, required for successful implementation of an ACO, will take more time to achieve than originally expected.

There are several models of ACOs to consider. The simplest is a virtual ACO model that requires less complicated legal organization between the various providers and hospitals. Integrated ACO models amalgamate insurance and care delivery roles to achieve incentives for efficient quality care. Successful examples of integrated ACOs include the Geisinger and Kaiser Permanente systems, which link efficiency, quality and insurance reimbursement.

The Medicare ACOs which are scheduled to begin in 2012 will require a formal legal structure. For statistical validity of quality measures, CMS requires that a minimum of 5000 Medicare beneficiaries participate in an ACO. The Medicare ACO will operate on a fee-for-service basis and will have defined quality and reporting standards. The law does allow partnerships with hospitals but all report data for quality and cost measures is required to be patient-centered. Payments will be related to the metrics reported and bonus reimbursements will be given for meeting certain levels of performance. The law will also allow states to develop ACOs for pediatric Medicaid recipients in 2012.

However, there are a number of unresolved issues for physicians before ACOs come into play. Many of these have potential medical-legal implications. Foremost of these is whether the format of these organizations will conflict with the Stark Law and anti-kickback legislation at both state and federal levels.

In addition, there are a number of insurance laws that may also conflict with the proposed structure of ACOs. Concerns include other important areas such as: the scope of potential medical mal-

practice actions – who is responsible? And if there is a partnership with hospitals, will their protected status cause greater problems for physicians? The American Medical Association along with state medical societies is working to ensure appropriate physician control over governance of ACOs and appropriate distribution of savings. We may see a proliferation of ACO models in the coming year. One size does not appear to fit all. As a physician, I feel we must advocate for immediate clarification and modification of the legal obstacles still in place so that physicians will be able to adapt comfortably to these changes.

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## CME Exam and Evaluation

### A Primer on Accountable Care Organizations

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#### Instructions for Requesting CME Credit

Please submit your test along with a check (see course fees below) made payable to the Massachusetts Medical Society, P.O. Box 9155, Waltham, MA 02354-9155, (phone: (781) 434-7306, fax: (781) 642-1246, email: [continuingeducation@mms.org](mailto:continuingeducation@mms.org).)

Participants seeking *AMA PRA Category 1 Credit™* will receive a confidential report of their examination score and the correct answers. A score of at least 70% is required to receive *1 AMA PRA Category 1 Credit™*.

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Massachusetts Medical Society (MMS) Member: \$10 (\$10 per credit)  
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Please answer the following questions. A score of at least 70% is required to receive 1 *AMA PRA Category 1 Credit™*. Deadline for completing the exam is February 28, 2012. Please make a copy for your records.

- The Medicare ACOs are currently scheduled to begin in January 2012.
  - a. True
  - b. False
- Medicare ACOs will be required to have a minimum of \_\_\_\_\_ Medicare beneficiaries.
  - a. 15000
  - b. 5000
  - c. 1000
- Stark Law regulations have been modified to exempt ACOs.
  - a. True
  - b. False
- In the virtual ACO model, hospitals, physicians and other providers must have a formal legal structure.
  - 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](mailto:continuingeducation@mms.org).

Did this activity meet the stated objectives?

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

- High
- 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.

\_\_\_\_\_

\_\_\_\_\_

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How do you rank the quality of this education program?

- High
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- 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?

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

# Discussing end-of-life care with patients

Continued from page 1  
of accidents.”

While a number of states have enacted “natural death acts” – codifications guaranteeing the right to refuse life-sustaining medical technology – there’s no such statute in Massachusetts, said Stancel.

But patients can elect this outcome, or something else, by creating the appropriate legal documents.

A health care proxy is a document where a patient designates someone else to make health care decisions if the patient is unable to make or communicate his or her own decisions. The proxy or agent cannot be an “operator, administrator or employee” of a hospital or nursing home where the patient is receiving care. The proxy is valid in Massachusetts if executed in conformity with MGL c. 105D, which requires that two witnesses also sign it.

A living will is a written statement of the patient’s wishes for end-of-life care, in the event that he or she cannot make health care decisions or communicate them directly.

Living wills may be considered evidence of a person’s end-of-life wishes. But according to Rockefeller, “Strictly speaking, in Massachusetts, living wills do not have the statutorily conferred authority of a health care proxy.”

## The conversation

In the June 2010 issue of Health Policy, re-

of the proxy and/or family, to make sure everyone’s on the same page.

He might start the discussion by giving patients what’s colloquially called “the blue form,” a one-page form created by the Massachusetts Department of Public Health Office of Emergency Medical Services that defines and elaborates what “Do Not Resuscitate” means, principally so that EMTs and other first responders know a patient’s wishes.

In addition, he often refers patients to the Massachusetts Medical Society website, which provides a health care proxy form and instructions. Further, Aging With Dignity’s website offers a “Five Wishes” form for patients. The Massachusetts Trial Court Library is another useful resource.

## The big picture

From a public policy standpoint, there’s a lot going on with regard to end-of-life issues in the Commonwealth, said Riley.

Evidence of this is Chapter 305, Sec. 42 of the Acts of 2008, which charged the state’s Executive Office of Health and Human Services to convene an expert panel on end-of-life care, to identify best practices and make recommendations.

Riley, a member of that panel, said, “The focus was not just on patients with serious, life-threatening illnesses, but on all patients and providing them with a full range of options for end-of-life care, from aggressively prolonging

## Resources on the web

- **Massachusetts Medical Society Health Care Proxy form and instructions:**  
<http://www.massmed.org/AM/Template.cfm?Section=Search&CONTENTID=2570&TEMPLATE=/CM/ContentDisplay.cfm>
- **Massachusetts Comfort Care/Do Not Resuscitate Order Verification:**  
[http://www.mass.gov/Eoohhs2/docs/dph/emergency\\_services/comfort\\_care\\_form.pdf](http://www.mass.gov/Eoohhs2/docs/dph/emergency_services/comfort_care_form.pdf)
- **Massachusetts Commission on End-of-Life Care:**  
[http://www.endoflifecommission.org/end\\_pages/about.htm](http://www.endoflifecommission.org/end_pages/about.htm)
- **Massachusetts Medical Order for Sustaining Life (Worcester County):**  
<http://www.molst-ma.org/forms>

— Jane Pribek

searchers at the Johns Hopkins Bloomberg School of Public Health in Baltimore reported that just 34 percent of respondents said they have an advance directive.

Lee, who also chairs the Massachusetts Medical Society’s Committee on Geriatrics, said that in his experience, many people don’t have them. But over the last five years, he’s seen an increase in patients who do, something he regards as a positive trend.

Lee typically talks to patients about end-of-life care within the first six months of seeing them.

“In the beginning I was very uncomfortable, because I was not accustomed to being as blunt about the subject with somebody who was well. But I’ve become more comfortable with the subject,” he said.

“I suspect that as my patients become more familiar with me, when I introduce the subject solely as a precaution so that I may deliver the type of care they want, they’re less uncomfortable with it,” Lee added.

He previously worked in a hospital setting and said it’s harder to raise the topic there, when the physician might be treating someone for the very first time and death is a more imminent possibility.

The need to talk about these issues early in treatment is especially great if a patient might have competency issues. Lee advises having the conversation in the office rather than the hospital setting, and in the presence

life on one end of the spectrum, to focusing almost exclusively on comfort as the inevitable takes place.”

The panel completed a 40-plus page report in the fall of 2009. However, its public release has been delayed. Riley hopes the report will be released soon.

In addition to creating the panel, that same law called for a public awareness campaign to highlight the importance of end-of-life planning.

And it created a pilot project to measure the effectiveness of the Medical Orders for Life-Sustaining Treatment (MOLST) form.

The MOLST, in conjunction with a proxy, goes beyond the blue form, informing health care providers what the patient wants to happen in various circumstances, discussing resuscitation, intubation and ventilation, hospitalization, respiratory support, dialysis support, and artificial nutrition and hydration. It’s two pages long and must be signed by both the physician and patient, or his or her proxy and/or guardian.

According to Riley, the MOLST has been used in Worcester County for over a year, has been deemed a successful experiment, and will likely be used elsewhere in the coming months and years.

Finally, Riley said continuing medical education on end-of-life care will likely become a licensing requirement for all physicians in Massachusetts within the next year or so. **MMLR**

## Avoiding liability in handling end-of-life care

In a perfect world, every patient would have clear, concise documents that designate a proxy who communicates his or her end-of-life wishes.

In the real world, however, this doesn’t always happen. Here are answers to some key questions to help physicians avoid legal liability in situations when the path is not entirely clear, from Boston attorney Regina S. Rockefeller of Nixon Peabody LLP, who represents and advises health care providers.

### Q: What if the physician questions the authenticity of end-of-life documents?

**A:** Under Massachusetts law, a health care proxy requires the signature of the principal and two adult witnesses. The document does not need to be notarized. If the health care provider is suspicious of the document’s authenticity, then he or she can, in some circumstances, compare the patient’s signature on the health care proxy or living will with another signature of the patient known to be authentic (such as a driver’s license, passport, medical consent forms or letters to the physician) to see if the signatures match.

### Q: What if there are two health care proxy documents?

**A:** Look at the dates of execution. Usually the more recent document will, by its terms, revoke and supersede a prior health care proxy.

### Q: Can/should health care providers disregard these documents if they were created in another state?

**A:** No. A physician should respect a document created in another state if it was valid under the laws of the state where it was executed.

### Q: What should the physician do if a living will’s instructions are contrary to a patient’s present stated wishes and there are signs that the patient’s competency is questionable?

**A:** A competent patient can revoke a health care proxy or living will. A physician should start with the presumption that the patient before him or her is currently competent, even if the patient may be slipping a bit. The patient’s currently stated oral wishes will, in most circumstances, govern until such time as the patient is legally declared incompetent by a court having jurisdiction or, if the patient has a health care proxy, until two physicians declare the patient unable to make health care decisions such that the authority of the designated proxy takes effect.

### Q: What should be done if the living will calls for an outcome that’s contrary to what the proxy is now saying should be done, and the patient is unable to communicate?

**A:** In Massachusetts, if a patient with a health care proxy has been declared by two physicians to no longer be able to make health care decisions, then the proxy holder will usually have the authority to make health care decisions for the patient. A physician can rely upon the decision of the proxy holder even if the proxy holder’s decision is at odds with the patient’s living will.

### Q: If there are no advance directives, can a physician forgo life-sustaining treatment if the patient cannot communicate that this is his or her wish, and a spouse or other family member says that it’s the patient’s actual or probable wish?

**A:** Yes. In some circumstances, where there is no advance directive, the physician can recommend that life-sustaining treatment be forgone.

### Q: What should the physician do if the patient cannot communicate, there is no health care proxy, and family members disagree on the level of life-sustaining treatment to be administered?

**A:** The physician should consider involving his or her hospital’s ethics committee for guidance. The physician should not just err on the side of sustaining life. Rather, the substituted judgment of the patient – what the patient would have wanted in these circumstances if the patient were suddenly lucid and able to communicate – should be discerned. In rare and highly contentious circumstances, seeking court approval may be considered.

### Q: Can a physician order the withholding or withdrawal of artificial fluids and nutrition from a terminally ill patient or permanently unconscious patient, if that’s what an advance directive calls for?

**A:** Yes. The physician can rely upon the judgment of the proxy holder, who should make this decision based upon his or her best judgment of what this particular patient would have wanted in the circumstances that the patient now occupies. Physicians also should become knowledgeable about the nutrition and hydration policies of the hospital, especially a religiously affiliated hospital, in which the patient seeks treatment.

### Q: Should the physician consult with the health care facility’s risk managers in all instances before ending life-sustaining treatments?

**A:** For the physician’s own protection in difficult cases, consulting with the facility’s ethics committee or risk managers may be advisable when ending life-sustaining treatment for a hospital inpatient. Strictly speaking, such prior consultation is not legally required but is often helpful.

### Q: Do you have any other advice or thoughts on end-of-life issues for physicians with regard to reducing their legal exposure in difficult cases?

**A:** If the physician is uncertain about an end-of-life decision in a particular case, the physician may protect himself or herself by involving others in the process and by documenting the deliberative process and the factors considered. The physician can talk to a competent patient, a health care proxy, a patient’s spouse/life partner, adult children, adult children of a deceased child of an incompetent patient, other physicians, hospital administrators, hospital legal counsel, the hospital’s ethics committee and risk managers, and/or clergy for the patient.

— Jane Pribek

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