

Rx FOR EXCELLENCE SEPT. 24 — HONOREES ANNOUNCED INSIDE — SEE PAGE 8

Board of Medicine releases new prescribing guidelines

First major revision of document since 2001



By Eric T. Berkman

The Board of Registration in Medicine has issued its first major revision to the state's prescribing guidelines in nearly a decade, giving Massachusetts physicians clearer guidance on what they can and can't do.

Any action the Board takes with respect to prescription practice is important because prescribing problems have always posed a serious ethical trap.

The new guidelines – which quietly took effect on May 19 – reflect both statutory and regulatory changes adopted at both the state and federal level, as well as changes in policy since the Board last revised the guidelines in 2001.

Significant changes include:

- A section on supervision of mid-level practitioners;
- The Board's policy on gifts and inducements from the drug and device industry;
- Guidelines on office-based treatment of drug addiction, as well as prescribing of controlled substances to treat pain; and
- An updated discussion of e-prescribing.

The goal was to combine "in one document what's already been the different elements of prescribing expectations and responsibilities," says Russell Aims, the Board's chief of staff. "By uniting [the piecemeal policy changes over the past decade] in a single document that we hope is more user-friendly and flows more logically, it'll make it easier for physicians to understand their responsibilities and the Board's expectations."

Massachusetts Medical Society President Alice Coombs applauds the Board's efforts. "[Prescribing practices] are an important piece

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Supreme Judicial Court weighs patient privilege

By Jack Dew

The Supreme Judicial Court heard oral arguments in May in a case that could alter the definition of the psychotherapist-patient privilege.

The Board of Registration in Medicine argues that it has reason to suspect that a Revere psychiatrist was abusing his prescribing privileges and giving patients inappropriate amounts of powerful painkillers. The Board contends that the privilege doesn't apply because the doctor wasn't acting as a psychiatrist, and has sought patient records from a

random sample of his patients.

The doctor responds that he specializes in the psychiatric treatment of patients who suffer chronic pain and says his patient records are protected by the psychotherapist-patient privilege.

In 2008, a Superior Court judge sided with the Board and ordered the doctor – identified in court papers as John Doe – to turn over the records.

The doctor appealed to the state Appeals Court, and the SJC took the case on its own initiative. Meanwhile, the Superior Court order has been stayed pending the appeal.

Privilege at stake

Lawyers who represent physicians argue that a crucial privilege is at stake in the case.

Dean P. Nicastro of Pierce & Mandell in Boston, who is not in



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Verdict for physician overturned by judge

Patient dies after surgery on knee

By Jack Dew

In a rare move, a Superior Court judge has overturned a jury's verdict in favor of a physician in a medical-malpractice case and ordered a new trial after concluding that the weight of the evidence did not support the verdict.

Following a trial in Middlesex Superior Court, a jury ruled that an orthopedic surgeon should not be held responsible for the death of a patient who suffered a massive pulmonary embolism days after undergoing knee surgery.

The plaintiff filed a motion for a new trial, which Judge

Thomas P. Billings granted.

The judge concluded that although the standard for ordering a new trial following a jury verdict is "undeniably stringent," the verdict in the case was "manifestly against the weight of the evidence, and that it is therefore my duty to set it aside and order a new trial."

History of complications

The patient in the case, John L. Howard, injured his knee while playing basketball in March 2004. He went to the emergency room where doctors found that he had ruptured his patellar tendon.

It was the second time that Howard had injured one of his knees. In 1998, he underwent surgery to reconstruct his ACL

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A primary care stimulus plan

In June, the Department of Health and Human Services announced \$250 million worth of investments intended to “increase the number of health care providers and strengthen the primary care workforce.”

This primary care improvement plan – which follows from the new federal health care reform law – is welcome news here in Massachusetts, where lengthy waiting lists and closed practices have become the primary care norm.

This shortage existed before the state’s



health care reform law went into effect in 2007. And the problem has become even more severe since then, as an estimated 600,000 previously uninsured patients having sought doctor appointments.

You may recall that my own search for a primary care physician in 2007 was an uphill journey that involved numerous medical offices with overflowing waiting rooms before I found my way to an internist.

The government plan is intended to make strides in changing all that – with a total investment of nearly \$2 billion over five years – projecting training for more than 16,000 new primary care providers over the next five years.

The current installment of \$250 million includes:

- \$168 million for creating more than 500 primary care residency slots;
- \$32 million for developing more than 600 new physician assistants;
- \$30 million for encouraging more than 600 nursing students to go to nursing school full-time, which increases the chances that they will complete their education;
- \$15 million for establishing and operating 10 nurse-managed health clinics to help train nurse practitioners; and

- \$5 million for states to implement new strategies to expand their primary care workforce by 10 to 25 percent over 10 years.

Editor’s Note

This stimulus money certainly seems like a big step in the right direction. But it’s only one piece of the

primary care puzzle.

What’s not clear is whether any increase in pay for primary care practitioners will be included. One of the reasons cited for medical students choosing specialties – and not primary care – is the pay grade. They enter medical school interested in pursuing primary care, but they exit selecting higher-paying specialties. They are concerned about future income, several surveys have found.

Anecdotally, students are also concerned about tougher working conditions in primary care, with elderly patients with a host of medical problems. And the physician shortage right now feeds itself. Fewer doctors seeing more patients means more work, and more burnout.

Let’s hope that the new funding is a start in a process of many changes to improve access to primary care providers.

— Reni Gertner, MPH

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Payment reform and delivery system reorganization are coming



By Craig D. Schneider, Ph.D

"Revolutionary" changes to the health care payment system and the structure of the delivery system are coming soon, several speakers told the audience at the Massachusetts Health Data Consortium's Annual Conference on June 4 at the Boston Logan Airport Hilton.

"If we don't do payment reform and control Medicaid spending, the wheels will come off Chapter 58 [the Massachusetts healthcare reform law enacted in 2006]," State Rep. Harriett L. Stanley said during the keynote address.

Speakers addressed different approaches to reforming the payment system and establishing "accountable care organizations," the term for actual or virtual integrated delivery networks that will be paid based on performance.

Several noted that the federal health care reform law contains provisions that will require providers to become more organized and to receive bundled or global payments.

Francois deBrantes, CEO of the Health Care Incentives Improvement Institute (HCI3), told the providers and health plan representatives in the audience that these provisions in the federal law constitute a "burning platform. If you're not feeling the fire under your feet, you're either delusional or you will have an unpleasant wake-up call in the next three to four years."

HCI3 is the parent company of the private-sector Bridges to Excellence and Prometheus pay-for-performance programs. Prometheus has developed more than 20 episode-based payment models for various treatments.

HCI3's approach and the direction that the Medicare

Craig Schneider is the Director of Healthcare Policy at the Massachusetts Health Data Consortium in Waltham.

program is going "are highly disruptive, but that's the point," deBrantes said.

Consortium CEO Ray Campbell agreed that "the fee-for-service payment system is the root of all evil in the health care system."

The speakers asserted that Massachusetts will lead the country on payment reform because the Commonwealth solved the access problem earlier than the federal government, and because the state is acutely feeling the pressure of rising health care costs.

"We are living through an historic, incredible time. Scientific fatalism is disappearing, as problems that seemed unsolvable, such as patient falls, infections and readmission, are being addressed by numerous providers," Tom Lee, President of Partners HealthCare System, said. "Massachusetts is on the forefront of covering everyone, but that puts costs front and center."

The pressure for payment reform comes from payer dissatisfaction with quality as well as cost increases, according to Cathy Schoen of The Commonwealth Fund. The goals of payment reform are to reward value rather than the volume of services, and to transform the delivery system to focus on population health, she explained.

Schoen added that the strategic reforms to achieve these goals are to strengthen primary care, to make providers accountable, to reward care coordination, and to use health information technology to improve quality and outcomes.

Technology improving quality of care

The afternoon panel was comprised of presumptive recipients of federal grants from the Office of the National Coordinator for Health IT. They addressed how HIT and health information exchange are critical elements for quality improvement and paying for value.

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Listening In

The news beat of the medical profession

U.S. recovers \$2.5B in Medicare fraud

The federal government announced that it recovered \$2.5 billion in overpayments for the Medicare trust fund last year as the Obama administration focused attention on fraud enforcement efforts in the health care industry.

Investigators have new tools this year to help crack down on health care fraud, with the Justice Department and the Department of Health and Human Services working cooperatively to police companies.

The newly enacted Affordable Care Act is designed to lengthen prison sentences in criminal cases and provides an additional \$300 million over the next 10 years for stronger enforcement. It also gives the government new authority to step up oversight of compa-



nies participating in Medicare and Medicaid.

Under the Act, providers could be subject to fingerprinting, site visits and criminal background checks before they begin billing Medicare and Medicaid.

To combat fraud, the Act allows Health and Human Services Secretary Kathleen Sebelius to bar providers from joining the programs and to withhold payment to Medicare or Medicaid providers if an investigation is pending.

Firms to pay \$81M for illegal drug promotion

A U.S. District Court magistrate judge has ordered two subsidiaries of pharmaceutical giant Johnson & Johnson to pay more than \$81 million after pleading guilty to illegally promoting the epilepsy drug Topamax for psy-

chiatric uses.

Magistrate Judge Robert B. Collins ordered Ortho-McNeil Pharmaceutical to pay a \$6.14 million criminal fine after pleading guilty to one count of a misdemeanor violation of the Food, Drug and Cosmetic Act for promoting Topamax for unproved uses.

Its holding company, Titusville, N.J.-based Ortho-McNeil-Janssen Pharmaceuticals Inc., will pay

\$75.37 million to resolve civil allegations under the False Claims Act.

Prosecutors say that the holding company hired outside physicians to join sales representatives in visits to health care providers and to speak at meetings and dinners about prescribing Topamax for psychiatric purposes, even though the uses had not been approved by the FDA.

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Study: EHRs help save lives



A study published in the online medical journal Pediatrics claims that that electronic health records and prescriptions can prevent medical errors and save lives.

A team of doctors from Harvard University, Stanford University and the Lucile Packard Children's Hospital in Palo Alto, Calif., claim that an electronic communication system in use at the hospital since 2007 has resulted in a 20 percent drop in the number

of patient deaths.

The hospital's computerized physician order entry (CPOE) system has cut the time it takes to relay prescriptions to pharmacists in half and resulted in the equivalent of 36 fewer deaths at the hospital over an 18-month period, the doctors said.

Most previous studies have found either no change or an increase in the mortality rate when such systems were implemented, according to the researchers.

Defense verdicts rule the day in Mass.

Continuing a trend, health care professionals won nearly all medical-malpractice disputes that went to trial in 2009.

According to a Massachusetts Medical Law Report review of every Superior Court case tried last year, nearly 90 percent of the med-mal disputes that went to trial were decided in favor of doctors.

In Norfolk County, all 12 of the court's med-mal trials ended with defense verdicts.

"I was appointed to the bench in 2001, and I have never presided over a medical-malpractice trial that resulted in a plaintiff's verdict," said Superior Court Judge Janet L. Sanders, who serves as Norfolk County's re-

gional administrative justice.

Likewise, Superior Court Judge Patrick F. Brady, who has presided over 26 med-mal trials since 1993, said he has had only one trial result in a plaintiff's verdict that exceeded a defendant's settlement offer.

Jeffrey N. Catalano of Boston's Todd & Weld, a plaintiffs' med-mal lawyer who secured one of only 11 plaintiffs' victories in the state in 2009, said that several attorneys have stopped representing patients in med-mal cases as a result of the trend.

"There is real juror hostility toward patients and plaintiffs who choose to pursue these cases," he said.

— David E. Frank

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MMS study: Physicians' practice climate in decline in Mass.

An analysis released by the Massachusetts Medical Society in May shows a prolonged decline in the state's

The index has declined in 16 of the 18 years that MMS has been compiling such data.



physician practice environment and points to continuing concerns affecting physicians that are likely to affect the delivery of care to patients.

MMS released its annual Physician Practice Environment Index, a statistical compilation of nine factors that influence the practice climate for physicians. For 2009, the index declined 0.8 percent, representing a continued deterioration of the practice environment for physicians in Massachusetts.

The four main factors causing the decline were: (1) a growing burden of professional liability rates on physicians; (2) an increasing use of emergency departments by patients; (3) an aging physician workforce; and (4) the increasing cost of maintaining a physician's practice.

According to MMS, the increasing professional liability rates and the rise in emergency department use by patients are the most troublesome issues.

FTC again delays 'red flags' rule enforcement

The Federal Trade Commission has once again delayed the enforcement of the "red flags" identity theft rule through Dec. 31.

The move comes at the be-

hest of members of Congress, who asked the agency to delay enforcement pending legislation that would affect the scope of entities covered by the rule.

The so-called "red flags" rule requires businesses that accept deferred payments from clients to create written policies outlining how they will prevent, detect and address identity fraud.

The rule originally went into effect on Jan. 1, 2008, with full compliance intended by Nov. 1, 2008. But the commission has delayed enforcement several times since then amid challenges to the rule's applicability and related legislation.

The rule was initially designed to apply to finan-

cial services businesses, but FTC officials said other businesses – including medical practices – would be covered as well.

The American Bar Association successfully delayed enforcement against lawyers by winning summary judgment in federal court in Washington, D.C. That ruling is being appealed by the FTC.

In May, the American Medical Association, along with several other physician groups, also filed a lawsuit, contending that health care organizations should not be included among businesses required to adopt new measures to protect customers from identity theft.

— Kimberly Atkins



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Rx FOR EXCELLENCE SAVE THE DATE — SEPTEMBER 24, 2010

Bills, Rules & Regs



From Beacon Hill

State Senate backs bill to control health costs

Wealthier hospitals would be required to make a one-time, \$100 million contribution to ease insurance premiums for smaller businesses under a bill passed by the state Senate.

The legislation allows businesses with 50 or fewer workers to form cooperatives to purchase insurance at a lower cost. Another provision presses insurers to spend at least 90 percent of premium dollars on care and 10 percent or less on administrative costs.

Under the bill, health insurers would have to file rate increases with the Division of Insurance three months before they are set to take effect. The DOI would be required to review the rates to see whether proposed increases are reasonable.

The bill also attempts to smooth out fluctuations in employer health care costs by requiring yearly age measurements and encourages small businesses to adopt wellness programs designed to help workers avoid getting sick.

Health bill opposed by taxpayer group

A Massachusetts Senate budget amendment aimed at curbing health insurance costs for cities and towns is “so deeply flawed that it should not be included in the final budget unless it is dramatically improved,” Mass. Taxpayers Foundation President Michael Widmer told lawmakers.

Widmer wrote in a letter to budget chiefs Sen. Steven C. Panagiotakos, D-Lowell, and Rep. Charles A. Murphy, D-Burlington, that the provision does not directly address escalating costs.

The proposal would permit city and town managers to unilaterally implement “plan design,” which permits them to set co-pays and deductibles for their workers, a process they argue could save \$100 million per year for their cash-strapped coffers.

Under the Senate plan, a quarter of the savings would automatically go to cities and towns, another quarter would go back to the workers in the form of premium or co-pay relief and the allocation of the remaining 50 percent would be negotiated between the municipality and the unions.

If an agreement is not reached within 45 days, an arbitrator would decide how to apportion the remaining 50 percent of the savings.

“The escalating costs of health insurance are such a major part of the problem and the solution that this issue must be addressed in a direct way, which the Senate proposal does not,” Widmer said.

House OKs use of drug coupons

The Massachusetts House of Representatives has unanimously approved a bill allowing consumers to use coupon or rebate offers to help lower the cost of prescription drugs.

Backers of the bill said that it would provide consumers with cost relief at a time when steep co-pays could deter patients from taking their full regimen of medications.

When patients don’t take necessary medicine, they end up in the hospital, causing health care costs to rise further, according to the bill’s sponsor, Rep. Peter J. Koutoujian, D-Waltham.

The House adopted an amendment proposed by Rep. Jason Lewis, D-Winchester, requiring the state Division of Health Care Finance and Policy to study the effects of the coupon bill and ensure that it doesn’t drive up demand for brand name drugs.

Rep. David Sullivan, D-Fall River, said that the bill would not supersede decisions by doctors who choose to prescribe generic drugs for their patients, and he emphasized that the state has policies in place to ensure that generic drugs are the first option for patients before more expensive brand name drugs are prescribed.

Last year, House members voted 48-108 to reject a similar proposal Sullivan offered as an amendment to the fiscal 2010 budget.

Koutoujian was among the voters against that proposal. He said that attaching the proposal to the budget would have been inappropriate and he chose instead to focus on getting the bill passed as separate legislation.

Insurer, state strike deal on rate hikes

In the ongoing legal battle over the Patrick administration’s move to block hundreds of proposed health insurance premium hikes for small businesses, the dispute with one of five major carriers has settled, according to state insurance officials.

The pact permits the insurer, Neighborhood Health Plan, to increase rates by an average of 7.7 percent across all of its offerings. The administration exchanged rhetorical blows with five major health insurers in March, after Insurance Commissioner Joseph Murphy, at Gov. Deval L. Patrick’s direction, rejected 235 of 274 proposed small business rate hikes he deemed “unreasonable” or “excessive.”

The agreement permits Neighborhood Health Plan to increase its rates by more than 7.7 percent for its products, as long as the average increase across all 19 of their products comes to 7.7 percent. That average includes the lower rates they were required to charge in April and May after Murphy rejected their initial proposals.

Patrick hailed the agreement as a successful attempt at avoiding an 11 percent rate increase, the highest increase Neighborhood Health Plan had charged. As part of the agreement, Neighborhood will withdraw pending appeals of the rate hike rejections, which were being adjudicated by Division of Insurance hearing officers.



From Capitol Hill

Top small biz lobby joins health plan suit

The nation’s most influential small business lobby has joined a court challenge to President Barack Obama’s health care overhaul, arguing that Americans cannot be required under the Constitution to obtain insurance coverage.

The National Federation of Independent Business announced that it has joined a federal lawsuit filed in Florida by 20 state attorneys general and governors, NFIB President Dan Danner said. All but one of the state officials are Republicans, and the case coincides with an election year.

At 350,000 members, NFIB boasts a far-reaching network of local activists. The group’s involvement ensures that constitutional arguments for overturning the health care law – even if they fail to sway federal judges – will be extensively aired in the fall campaigns.

Legal scholars are divided over prospects for the case. Many expect the administration to prevail.

FDA educates health care providers on misleading ads

The Food and Drug Association has launched an initiative aimed at educating health care providers about their role in helping to prevent false and misleading prescription drug advertising.

The “Bad Ad Program” is aimed at educating physicians and others in the health care field on how to spot inaccuracies in advertising and inform the agency.

“The Bad Ad Program will help health care providers recognize misleading prescription drug promotion and provide them with an easy way to report this activity to the agency,” said Thomas Abrams, director of the agency’s Division of Drug Marketing, Advertising, and Communications, in a statement.

The first phase of the initiative will involve distributing educational materials through medical societies and targeting health care providers at specifically-selected medical conventions.

Then, the FDA will expand its collaborative efforts and update the educational materials over time.

Reports of potential FDA violations in drug

promotions can be sent to the agency at badad@fda.gov or calling 877-RX-DDMAC.

Reports can be submitted anonymously; however, the FDA encourages providers to include contact information for follow-up, if necessary.

– Kimberly Atkins

Groups lobby for more time for EHRs

Health care providers need additional time and greater flexibility to meet criteria of the Centers for Medicare and Medicaid Services’ proposed electronic health record rule, a coalition of 51 groups told Health and Human Services Secretary Kathleen Sebelius in May.

HealthLeaders Media reported that the coalition, which includes the American Hospital Association, the American Medical Association, the American Academy of Family Physicians, the American College of Physicians, the American Psychiatric Association, the Association of American Medical Colleges and the Medical Group Management Association, wrote that while they “fully support” the purpose of the American Recovery and Reinvestment Act of 2009 to “encourage the adoption and use of EHRs,” the mandated deadline is “unrealistic.”

The requirements are asking for too much, too soon, they argued. Specifically, the organizations said the requirements include advanced functions such as computerized physician order entry, clinical decision support and electronic medication reconciliation, which generally occur at the end of a multi-year transition to EHRs.

The coalition’s letter parallels many concerns expressed by both House and Senate members in letters sent in March to the acting CMS administrator. Like Congress, the groups are asking to extend the required transition to meaningful use to 2017, consistent with stimulus legislation.

FDA unveils draft transparency proposals

As part of a Food and Drug Administration initiative to help consumers, stakeholders and others understand how the agency operates and makes decisions, a task force has unveiled 21 draft transparency proposals for public comment.

The proposals, released in an FDA report in May, are part of the FDA’s Transparency Initiative launched last summer by Commissioner Margaret A. Hamburg, M.D.

“Our goal is to facilitate transparency that promotes public health and innovation,” said Joshua Sharfstein, M.D., FDA principal deputy commissioner and chair of the Transparency Task Force, in a statement announcing the proposals. “These proposals reflect a careful balancing of the importance of transparency with the importance of protecting trade secrets and confidentiality.”

The draft proposals deal with issues ranging from the agency’s docket management process, product applications, recalls, inspections and importing requirements.

The proposals were drafted after the task force reviewed more than 1,500 public comments, and after consideration and discussion within the agency.

Those seeking more information on the proposals or to comment can do so on the FDA’s website.

– Kimberly Atkins

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Uncertified medical expert's opinion is admissible

By Thomas E. Egan

Expert evidence in a medical-malpractice case against an obstetrician should not have been excluded merely because the expert was not board-certified in obstetrics, the U.S. Court of Appeals for the 1st Circuit has ruled.

The trial judge found the witness unqualified to give his opinion on an obstetrician's alleged departures from the standard of care.

But the 1st Circuit said that the expert's opinion was admissible.

"The dispositive question is not whether an expert is board certified in a particular medical specialty," Judge Kermit V. Lipez wrote. "Rather, the [Federal] Rules of Evidence require that the judge admit expert testimony relevant to the disposition of the case when it will assist the [judge or jury] in understanding a fact in issue and rests on a reliable foundation."

Attorney David Efron of Puerto Rico represented the plaintiffs. He was opposed by Eugene F. Hestres-Vélez, also of Puerto Rico.

Tragic delivery

The malpractice complaint claimed that the plaintiffs' son, identified as G.P.P., suffered catastrophic injuries during and immediately following his birth because of the negligence of Dr. Antonio Ramírez-González, the obstetrician who performed the delivery.

When Dilma Pagés-Ramírez's labor did not progress after arriving at the hospital, she was given intravenous Pitocin. Her water was artificially broken and an epidural anesthetic was started.

When the mother was fully dilated, an attempt was made to use vacuum extraction to deliver G.P.P. That attempt was unsuccessful, and the doctor eventually delivered G.P.P. by Caesarean section.

The baby was in critical condition when he was delivered. He has permanent brain damage and has been diagnosed with cerebral palsy.

The plaintiffs' complaint alleged that the physician departed from the standard of care by, among other things, failing to elicit a comprehensive obstetrical history from Pagés-Ramírez, failing to estimate G.P.P.'s fetal weight and to enter it into the delivery record, attempting a mid-pelvic delivery by vacuum extraction, failing to use an internal fetal heart monitor, and failing to timely call for a C-section.

Lack of board certification

The plaintiffs called their two medical experts – a specialist in neonatal/perinatal medicine (Dr. Carolyn Crawford) and a neurologist.

However, the trial judge limited the testimony of each, ruling that the witnesses were not qualified to offer testimony on either the appropriate standard of care for an obstetrician, or on the issue of whether any deviations from the standard of care caused the injuries to G.P.P.

The court cited Crawford's lack of board certification in obstetrics and gynecology and her statement that it is typically an obstetrician/gynecologist who "makes the final decisions regarding a woman in labor."

As a result, it ruled that the expert would not be permitted to "testify as to the events that occurred before and during the Cesarean section," and that she could not "provide any testimony pertaining to the cause of [G.P.P.]'s injuries."

Without the testimony of those medical experts, the plaintiffs did not have enough evidence to support their claims. As a result, the physician was awarded judgment as a matter of law.

Expert opinion allowed

On appeal, Judge Lipez said that the trial judge's reasoning – that "because Dr. Crawford herself is not certified to administer Pitocin or perform C-sections, she would not be qualified to opine on the alleged departures from the standards of care committed by Ramírez-González, an obstetrician-gynecologist" – was an abuse of discretion.

Although credentials such as board certification in a particular medical specialty may indicate that an expert's opinion is "entitled to greater weight," certification is not a prerequisite to qualification as an expert medical witness, Judge Lipez said.

"Dr. Crawford's credentials easily meet and, indeed, surpass the standard for admissibility of expert testimony," he said. "She is board-certified in, and practices, perinatal and neonatal medicine [and] has published book chapters that deal with the administration of Pitocin."

"She has served as a consultant at high-risk deliveries and has recommended that C-sections be performed [and] conducts peer review evaluations that involve taking into account the obstetrical and delivery care that a patient is given, and she has worked on guidelines for responding to perinatal emergencies," the judge added.

Judge Lipez also found that the witness's knowledge "rests on a reliable foundation" –



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her medical education and many years of experience in the field.

"Indeed, without Dr. Crawford's testimony on causation and the standard of care, the plaintiffs were unable to present evidence on two elements of their case," he concluded. **MMLR**

Questions or comments may be directed to the writer at: tom.egan@lawyersweekly.com



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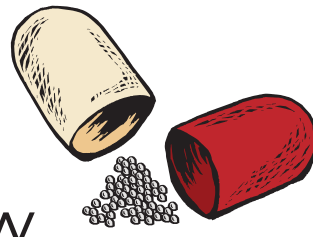
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Good Medicine

What doctors are talking about now



Q: Public Citizen recently released its annual report evaluating the work of state medical boards in disciplining doctors. Is the group's analysis helpful to patients and/or fair to physicians and state medical boards?

"These statistics are probably not useful to the average patient. What is useful is the publishing of information regarding individual doctors, so that patients can make an informed decision before seeing a particular doctor. This review and analysis really does not do that. But I do not think that such an evaluation is unfair to doctors directly, as it is geared more to the Board that oversees them. Anything that will increase reasonable scrutiny over doctors, lawyers or other professionals is necessary to protect the public they serve."

— **Robert Shuman, solo practitioner concentrating in medical negligence cases, Sharon**



"Regulation of safety and quality in the nation's hospitals and health systems has become increasingly standardized and their performance publicly reported. In stark contrast, the nation's 69 diverse, freestanding state licensing boards adhere to very few common practices, policies or validated measures. These authorities are only beginning to embark across the chasm of quality and safety. A very crude measure, 'discipline' events are nevertheless the only publicly available data regarding the actions of these authorities. The headline-grabbing annual 'ranking' is quite misleading, neither helpful to patients, fair to physicians nor a valid measure of a state medical board's performance. The adoption of national standards and processes in medical licensing is urgently needed."

— **Dr. John Herman, M.D., former chair of the Board of Registration in Medicine**



"Public Citizen provides no evidence to support its contention that the number of serious disciplinary actions per thousand doctors licensed by a state constitutes a meaningful evaluation of the work done by medical boards, or that it reflects the quality of care provided. Meaningful patient safety factors include: quality of the initial licensing application reviews; ongoing oversight of clinical practice; and availability of non-disciplinary remediation programs. The ideal practice environment would involve little or no serious discipline of physicians. The Massachusetts Department of Public Health, Board, and Medical Society have all worked to develop programs to protect patients. The Public Citizen ranking does not reflect any of this information."

— **W. Scott Liebert, Newton, former chief of litigation for the Board, represents doctors**



"Because medical boards are historically reluctant to publicize information about physician misconduct, having Public Citizen as a tool to promote user-friendly access to in-depth information is crucial. As long as the presented information is comprehensive, the material is beneficial. If part of public policy is to reduce the cost of health care, then reducing the likelihood of medical malpractice suits must be a part of the equation. Information such as that provided by Public Citizen can help reduce the number of lawsuits by allowing citizens to choose the best doctors."

— **Rep. Cleon H. Turner, D-Dennis, member of the Joint Committee on Public Health**



Public Citizen's analysis of medical boards: fair or foul?

By **James Feldman, MD, MPH**

Massachusetts is lax in disciplining problem physicians, and our state medical board ranks among the 10 worst in the nation in taking serious disciplinary actions against doctors. So says Public Citizen, a national nonprofit describing itself as a government watchdog.

It's appropriate to look critically at the group's rating system and to consider whether using the rate of disciplinary actions against physicians is a good way of assessing the performance of state licensing boards.

The agency's Health Research Group, one of whose stated purposes is to "push medical boards to do a better job of disciplining doctors," has over the last decade annually calculated the rate of "serious disciplinary

actions" (revocations, surrenders, suspensions, and probation/restrictions) taken by state boards. Using data from the Federation of State Medical Boards, the group assesses all states, highlighting the best and worst.

In its latest analysis, issued in April, it ranked Massachusetts 46th out of 50, with 1.93 serious actions per thousand physicians.

The state dropped a whopping 23 places from its 2001-2003 position, prompting Sidney M. Wolfe, MD, director of the Health Research Group, to suggest that the state has relaxed its discipline of physicians.

"Almost a 50 percent decrease in three years," he told *The Boston Globe*, "cannot be explained on the basis [that] suddenly the doctors in Massachusetts have gotten better."

Public Citizen issues this disclaimer: "This report ranks the performance of medical boards by their disciplinary rates; it does not purport to assess the overall quality of medical care in a state or to assess the function of the boards in other respects."

Although the report comes with a "warning label," the message is clear: state boards with lower disciplinary rates do a poor job policing physicians. This kind of analysis can have serious consequences.

It can paint the reputation of the state medical board (Is it doing its job properly?). It can characterize the physician workforce (Are Massachusetts doctors better or worse than their counterparts elsewhere?).

It also has implications for patients (Are quality care and patient safety

top concerns of physicians and medical boards?). It can color the all-important physician-patient relationship (Can patients trust their physicians to provide high quality, safe care?). And with the report generating sensational headlines, legislators and regulators may enact reforms in response.

Flawed analysis

To construct the rankings, Public Citizen takes the number of serious disciplinary actions and divides it by American Medical Association data on the number of doctors in a state.

"We add to this denominator the number of osteopathic physicians for the 37 boards that are combined medical/osteopathic boards," the group says. "We then multiply the result by 1,000 to get board disciplinary rates per 1,000 physicians. This rate calculation is done for each year and the average rate for the last three years is used as the basis for this year's state board ranking."

As well intentioned as the effort might be, the analysis is flawed.

Crude rates don't and can't tell the whole story. Statisticians would say that numbers taken out of context are meaningless. A fancier term is "adjusting for confounders." For example, comparing the crude death rates from car crashes among states would not be meaningful without considering the many factors associated with risk of death in a car crash, such as highway speeds, miles driven and number of drivers. The same applies to comparing rates of disciplining doctors.

The Commonwealth has far fewer physicians engaged in patient care than the nearly 37,000 Public Citizen uses in its calculations. Data from the Board of Registration in Medicine in April show 26,225 physicians with a full and active license and a local business address.

But even that figure is likely too high. Many physicians in Massachusetts work in academia, biotechnology or research and do not

care for patients or do not practice full time.

Massachusetts Health Quality Partners, a broad-based health care coalition, shows some 17,000 physicians in active practice in its database, which includes all doctors who submit claims to insurers for treating patients.

But even with better data, the analysis would fall short. Context is critical.

For example, patient complaints – the first step in any possible disciplinary action – are down by more than a third in the last three years, a fact acknowledged by the Board but not by Public Citizen.

Further, Public Citizen's analysis omits any influence of a longtime, effective patient safety movement in the state. Massachusetts has been a national leader in such efforts.

The Massachusetts Coalition for the Prevention of Medical Errors, the Betsy Lehman Center for Patient Safety and Medical Error Reduction, the Institute for Healthcare Improvement (as well as the Board's own Patient Care Assessment Division) are just some of the local groups, along with hospitals, whose work has put the state at the forefront of patient safety.

Physicians clearly support appropriate intervention for colleagues who engage in improper behavior, fail to meet clinical standards, or put patients at risk. Each case deserves its individual hearing, assessment and disposition. Discipline is only one tool in public protection.

The oversight of the practice of medicine is a complex endeavor that cannot be adequately judged by raw numbers and simple division and multiplication. It calls for objective analysis and context.

An evaluation such as Public Citizen's does a disservice, not only to the Board of Registration in Medicine, but also to physicians, and – most importantly – to patients.

James Feldman, MD, MPH, an emergency physician at Boston Medical Center, is chairman of the Massachusetts Medical Society's Committee on Quality of Medical Practice.

Doctor's Rx



Supreme Judicial Court weighs patient privilege

Continued from page 1

involved in the case but represents physicians, said that the Board should tread carefully when it seeks to pierce the privilege that exists between any caregiver and a patient.

"The patient-physician confidentiality relationship is an extremely important one in the practice of medicine," he said. "There are important principles at stake not just to the physician, but to the practice of medicine generally."

Paul R. Cirel of Dwyer & Collora in Boston, who represents the physician in the case, said that Massachusetts is a state of few privileges, protecting only communications between clients and their attorneys, the penitent and their clergy, and patients and their psychotherapists.

"Clearly, the idea behind the privilege is to create a place for people who are in need of a safe haven, a place where they can unload their darkest and deepest secrets without fear that someone else will be looking at them," Cirel said. "We think this is so important in Massachusetts that we made it one of the few privileges that we have, and it seems to me that if it were to be eroded or undermined, it would have to be by an act of the Legislature and not the Board of Registration in Medicine."

Ellen J. Messing of Messing, Rudavsky & Weliky in Boston called the case "scary, because the Board seems to be taking the position that they can micromanage the characterization of a psychiatrist's practice."

Further, "people who are suffering from emotional difficulties should be free to unburden themselves to learned professionals," she said.

Obligation to investigate

But the Board argues that it is obligated to investigate potential medical misconduct and can only do that with access to medical records. It also claims that the doctor was acting as a physician and not as a psychiatrist, and thus the therapist privilege should not apply.

In an amicus brief submitted on behalf of the Federation of State Medical Boards, Timothy C. Miller, a Dallas attorney, argues that

"the protection of the public requires that the Board have timely, unfettered access to patient medical records of the physician under investigation."

While the psychotherapist-patient privilege "provides confidentiality for statements patients make for the purpose of diagnosis or treatment," he wrote, it "is not an absolute privilege; instead, it is a qualified privilege that gives way for other stronger public policy concerns."



"The idea behind the privilege is to create a place for people who are in need of a safe haven, a place where they can unload their darkest and deepest secrets without fear that someone else will be looking at them."

— Paul R. Cirel of Dwyer & Collora, Boston

"The allegations in this case are very serious," Miller added. "If the allegations are true, the physician is a danger to society. The citizens of Massachusetts created the Board for this very possibility. Courts must balance public policies, but this maxim remains true—'The protective privilege ends where the public peril begins.'"

Assistant Attorney General Daniel J. Hammond, who represents the Board, declined to comment through a department spokesman. The Board of Registration in Medicine also declined to comment.

Board investigation

The conduct of "Dr. Doe" first came to the attention of the Board when one of his patients sought treatment from another doctor for an addiction to pain medication.

That doctor contacted Doe and asked why he had prescribed the patient Percocet. He later told the Board that Doe was "unable to respond satisfactorily to his questions and 'seemed unable to comprehend'" them, leading that doctor to suspect that Doe "may be cognitively impaired," according to the Board's brief.

The Board reviewed Doe's prescribing practices and found that he had written pre-

practice" during an interview with an investigator: "He accepted payment only in cash and did not accept insurance ... he accepted only patients who were referred to him by other patients [and] ... he scheduled no appointments, but rather conducted 'open' office hours three days per week."

When Doe refused to turn over his records, the Board sought relief in Superior Court, which Doe opposed, arguing that the records were protected by the psychotherapist-patient privilege.

When the Board argued that Doe had admitted that he was spending the bulk of his practice as a physician and not a psychiatrist, Doe sought an evidentiary hearing.

Judge Charles T. Spurlock denied the request, ordering Doe to turn over the records.

'Brushing aside' the privilege

In his appeal on Doe's behalf, Cirel argues that the Board has mischaracterized his client's practice while ignoring the clear privilege carved out by the Legislature to protect Doe's patient information.

"The Board improperly seeks to brush aside a well established privilege and asks this court to give it *carte blanche* to examine all patient treatment records maintained by a psychiatrist," Cirel wrote. "The privilege does not allow such disclosure and this court may not add exclusions beyond what the Legislature has deemed appropriate."

But the Board responds that the psychotherapist-patient privilege should not apply because "the Board's need for the requested records, in furtherance of its core function of protecting the health and safety of the public, would have overcome the assertion of the privilege in this case."

Regardless, the Board argues that state law defines a psychotherapist as someone who spends a "substantial portion" of his time in that capacity, and it claims that Doe does not meet that definition.

But Cirel argues that "a board-certified psychiatrist must qualify as a 'psychotherapist'" under state law. **MMLR**

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

Verdict for physician overturned by judge

Continued from page 1

at Framingham Orthopedic Associates.

Six-and-a-half weeks after that surgery, Howard's leg became swollen, and an ultrasound detected deep vein thrombosis. He was admitted to the hospital where he was treated for four days with an anti-coagulation drug.

For the 2004 injury, Howard returned to Framingham Orthopedic Associates where Dr. Peter B. Brassard performed the second surgery on March 29. On April 15, Brassard saw Howard for a follow-up exam and concluded that he was "doing fairly well."

Two days later, however, Howard was found dead in his home, the victim of a massive pulmonary embolism in which a large clot is believed to have formed in his leg, broken loose and traveled to his lungs, blocking the pulmonary artery or one of its branches.

Howard's estate sued, claiming that the doctor failed to take into account the patient's previous history of blood clots and failed to prescribe medication that could have prevented the embolism.

Family history

At trial, the plaintiff introduced evidence showing that a nurse had noted in Howard's file that he had suffered deep vein thrombosis after his 1998 operation, and Howard filled out a standard questionnaire in which he revealed he had a family history of "blood clotting disorders."

But Brassard testified that he customarily asked patients if they had had any significant medical issues and that "Mr. Howard

must have said no or they would be reflected on the form." He did not ask Howard about the outcome of any prior surgeries.

The plaintiff argued that Brassard should have known of the prior problems and

"That a surgeon, about to operate on a knee and knowing that the patient had undergone surgery on the other knee a few years before, would not ask anything about the outcome and about any complications is surprising."

surgeries and any complications. The expert responded, "That's a question I think that most surgeons would ask."

When questioned by the defense lawyer after that on whether Brassard's failure to ask

— Judge Thomas P. Billings

should have given Howard an anti-coagulant to prevent a recurrence.

Brassard and experts for both sides agreed that the standard of care in 2004 "required that a surgical patient known to have this history be anticoagulated prophylactically following surgery."

The plaintiff's expert testified that Brassard should have asked about clotting in the past and, when he learned of the family history of clotting disorders after the surgery, should have probed for more information.

But it was the defense expert's testimony that may have been essential. On cross-examination, the expert was asked whether a surgeon should have asked about previous

those questions was a deviation from the standard of care, the expert responded, without elaborating, "I don't think it is necessarily. No."

The jury returned a verdict for the physician, attaching a note that read: "While we believe Dr. Brassard had some responsibility in Mr. Howard's death, based on lack of evidence we were unable to determine that Dr. Brassard's actions deviated from [the] standard of care & treatment."

Weight of the evidence

The plaintiff's attorney, Michael S. Appel of Sugarman, Rogers, Barshak & Cohen in Boston, filed a motion for a new trial, arguing that the jury's finding was against the

weight of the evidence.

He leaned heavily on the testimony of Brassard's own expert and on Brassard's testimony that, in his experience, "if somebody has had a significant complication related to a prior surgery ... they'll tell you right up front very quickly."

Appel wrote that "it is clear that the evidence was overwhelming in favor of a verdict on behalf of the plaintiff and that the jury's finding that there was no negligence was greatly against the weight of that evidence. Moreover, the jury's statement that Dr. Brassard was partly 'responsible' for John Howard's death tends to indicate that their failure to find for the plaintiff was the result of bias, misapprehension or prejudice."

Judge Billings agreed.

Though he noted that "one must always beware, especially in a professional negligence case, of Monday-morning quarterbacking," he found that the evidence demonstrated that Brassard should have availed himself of the medical information obtained by the nurse or should have asked the patient about prior complications.

"That a surgeon, about to operate on a knee and knowing that the patient had undergone surgery on the other knee a few years before, would not ask anything about the outcome and about any complications is surprising, to say the least," the judge wrote. "Even ... the defense expert testified that 'most surgeons would ask about these things.'" **MMLR**

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

Verdicts & Settlements

Patient suffers cardiac arrest following colonoscopy

A 58-year-old husband and father underwent a routine colonoscopy in 2007.

Later that day, he developed significant abdominal and left shoulder pain and went to the ER early in the evening.

X-rays were normal. The patient remained in the ER overnight, receiving narcotic pain medications and fluids for his ongoing abdominal pain and nausea. The next morning, as he was being prepared for an abdominal CT scan, he went into cardiac arrest.

It was determined that the patient had suffered a ruptured spleen during the colonoscopy and had experienced massive internal bleeding. The patient was resuscitated but not before sustaining severe anoxic brain injury. He was hospitalized until his death approximately 18 months later from complications of his brain injury.

The plaintiff brought claims against the ER physician, hospitalist and covering gastroenterologist that the patient's symptoms were suggestive of an internal bleed or perforation and required an ab-

dominal CT scan.

The doctors maintained that splenic injury is an extremely rare complication of colonoscopy and that the plaintiff's stable hemodynamics, unremarkable physical exam and X-rays were not consistent with an ongoing bleed, which they claimed occurred the following morning.

The plaintiff claimed that the hospital's computerized patient access records and pager records established a timeline for the patient's care and the defendants' actions that was inconsistent with some of the accounts given by the hospital.

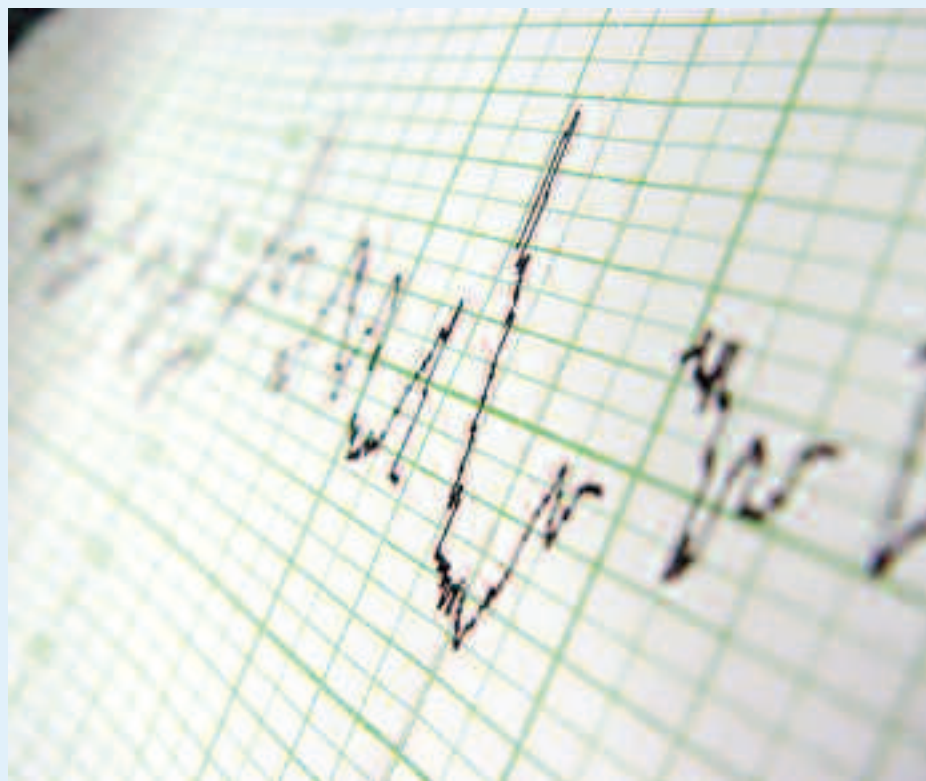
The case settled for \$4 million.

Type of action: Medical malpractice

Injuries alleged: Ruptured spleen following colonoscopy resulting in brain injury and death

Date: February 2010

Submitted by: Jodi M. Petrucelli and Benjamin R. Zimmermann, Sugarman & Sugarman, Boston (for the plaintiff)



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Suicidal patient escapes from hospital and dies

A 36-year-old known suicidal patient was transported involuntarily to the ER and subsequently admitted. Upon arrival, he was examined by an ER physician and two psychiatric clinicians.

Following their evaluation of the patient, the doctors' plan was to transfer him to a secure inpatient psychiatric unit. Unfortunately, no bed was available, so the patient remained in the ER overnight under observation.

The next morning the hospital nursing staff and psychiatric clinician found the patient to be calm and cooperative. After a discussion with the patient, the psychiatric clinician spoke with one of the two ER physicians on duty, who authorized the discharge of the patient to a non-section 12 psychiatric facility.

The discharging physician never examined the patient nor spoke with him prior to authorizing the discharge. The following morning, the man escaped from the facility and died.

The patient's estate alleged that the physician who authorized the discharge breached the standard of care when he discharged the patient to an inappropriate facility. The estate established through expert testimony that a qualified medical professional was required to evaluate the patient to determine whether he remained in need of section 12 protection. The experts further testified that the psychiatric clinician who examined the patient was not a qualified medical professional as required by the statute, and that the patient was transferred to an inadequate facility from which he escaped and died within 24 hours of his discharge.

The defense focused on the alleged change in the man's condition on the date of the discharge, and that the change warranted a lifting and/or withdrawal of the section 12 order.

The jury deliberated for approximately 12 hours before returning a verdict in favor of the patient's estate and against the ER practice group.

Type of action: Medical malpractice
Injuries alleged: Wrongful death, loss of consortium

Date: March 2010

Submitted by: Robert D. Stewart and Debora A. Concepcion, Parker Scheer, Boston (for the plaintiff)

Man has heart attack after work-related knee surgery

A 43-year-old millwright who suffered from diabetes and Addison's disease had recovered from a heart attack a few months before taking a new job performing maintenance and construction work at a local airport.

The power demand in the room where the man was working for a time periodically tripped the electrical supply, causing all power and lights to shut off. On one such day, as he walked along the darkened pathway to retrieve some materials for a job at another location, he banged his knee on a conduit that was protruding out of the wall into the pathway. He fell to the ground, complaining of an injury to his right knee. He reported the accident but continued to work.

Approximately two weeks later, the man was installing an elevated conveyer belt when his right knee made an audible pop. He stopped working and sought medical care.

An MRI revealed a torn medial meniscus. After several months of conservative treatment with no improvement, the man elected to have surgery. In preparing for the procedure, he stopped taking his aspirin, which was prescribed for his heart condition.

The knee surgery was performed successfully. However, on the following day, the patient suffered a second major heart attack. Two-and-a-half years following the surgery,



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the patient suffered a third, fatal heart attack.

Plaintiff's counsel was prepared through expert testimony to tie the heart attack suffered after the knee operation specifically to the need for surgery. Another doctor associated the third heart attack and death to the accident.

The defendants argued that the first event did not result in the torn meniscus. Rather, they contended, it was the second popping event that resulted in the injury. The defendants' experts were prepared to argue that given the worker's prior heart condition, he was in poor health and ultimately would have suffered a fatal heart attack regardless of the events surrounding the accident.

The case settled for \$350,000.

Type of action: Negligence & tort

Injuries alleged: Wrongful death, loss of consortium

Date: April 2010

Submitted by: Brian C. Dever, Keches Law Group, Taunton (for the plaintiff)

Patient claims untreated hemorrhoid led to cancer

The patient, 35, sustained a second-degree vaginal tear while giving birth to her second child. During the repair, the doctor noticed a large hemorrhoid and told a nurse midwife to have it evaluated with a possible GI consult to rule out a mass.

The next day, the patient was examined by another doctor and midwife. The agreed upon plan was to defer a GI consult and follow up with the primary care physician in a few weeks.

About a month later, the patient saw her primary care physician, who noted that her exam was negative for hemorrhoids and instructed her to call back if there was a recurrence. The patient had no recurrence of hemorrhoids and did not follow up with her doctor. Instead, over the next four years, she sought care from her gynecologist, but had no rectal examinations.

Almost five years later, the patient presented to her primary care physician with complaints of rectal bleeding with bowel movements. The doctor noted that there were no external hemorrhoids but that a rectal mass was present. The patient was referred for a GI consult and biopsy which showed intramucosal adenocarcinoma.

A chest CT scan revealed a 9.4-millimeter

nodule in the right lower lung lobe suspicious for metastasis. An abdominal CT scan and a PET scan showed likely liver metastasis. A liver biopsy confirmed adenocarcinoma of the liver.

The patient began chemotherapy treatments followed by chemoradiation and an abdominal perineal resection, left lateral segmentectomy of the liver, cholecystectomy and appendectomy. As of the time of the settlement, she was doing well and not receiving any treatment for her cancer.

Man develops Stage III cancer at excised mole site

The patient, 26, presented to a dermatology office with a mole on his upper back. The pathologist diagnosed the mole as a "severely dysplastic nevus (atypical melanocytic hyperplasia) with features of Spitz nevus."

The pathology report stated that the "nevus extends to one superficial and deep margins." A complete excision was recommended and the patient returned as directed. The pathologist reviewed the additional tissue and reported "cicatrix showing residual severely dysplastic compound nevus with features of Spitz nevus. Presence of epidermal invasion, mitosis and atypia are suspicious for progression to the aplasia. Nevus appears excised. Suggest follow up." The patient returned to the dermatologist twice over the next six months but was subsequently lost to follow-up. While he was supposed to be followed, he didn't return after six months time, and the office had no system in place to contact him.

Two years later, the patient noticed a "cyst" on his back near the scar from the previous excision. A biopsy performed at a local hospital revealed the mass as metastatic melanoma. Subsequently, the slides from the original biopsy and excision were obtained and reviewed as showing "melanoma, superficial spreading type, invasive to a depth of a minimum of 1.0 mm, anatomic Level IV; extending to inked deep resection margin."

The patient underwent a wide local excision and was diagnosed with Stage III melanoma. He underwent neck and back radiation treatments and high-dose alpha Interferon treatments, followed by high-dose Interleukin-II and chemotherapy.



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Treatment was unsuccessful and the patient died.

Experts were prepared to testify that the cancer had progressed from Stage pT-IB to Stage III by the time he was finally diagnosed and that his chances for cure would have been 94 percent with no nodal involvement and 73 percent with nodal involvement, but had progressed to a point at the time of diagnosis where the chance for a cure had dropped to less than 5 percent.

After conclusion of the depositions of

the defendants, the parties entered into negotiations that resulted in a settlement of \$1.75 million

Type of action: Medical malpractice
Injuries alleged: Delayed diagnosis of melanoma

Date: May 2010

Submitted by: Robert A. Shuman and Risa Schneider, Law Offices of Robert A. Shuman & Associates, Sharon (for the plaintiff)

cancer found at diagnosis was in a different place than where the hemorrhoid was noted years earlier.

The parties settled for \$1 million.

Type of action: Medical malpractice
Injuries alleged: Delay in diagnosis of colorectal cancer

Date: April 2010

Submitted by: Andrew C. Meyer and William J. Thompson, Lubin & Meyer, Boston (for the plaintiff)

The patient contended that the primary care doctor should have followed up on the finding in the rectum, to diagnose the cancer much earlier.

The doctor contended that the finding at childbirth was a simple hemorrhoid, and that it went away, as most hemorrhoids do, after the delivery. He also claimed that the absence of any symptoms for four and a half years indicated that the cancer could not have been present in 2000.

The defendants also contended that the

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.

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Course Information

Intended Audience

This course is intended for physicians and allied health professionals.

Course Objectives

- Define issues related to the current make-up of medical staffs for physicians and other health care providers.
- Propose plans to improve medical staff bylaws for the benefit of physicians, allied health care providers and patients.
- Explore the impact of the changing medical staff environment on the quality of patient care and peer and/or patient communication.

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Dealing with the changing dynamic of the medical staff



By Dean P. Nicastro, Esq.

In recent times, the organized medical staff has evolved from an almost exclusive model of community-based

independent physician practitioners to include a number of other physicians who have hospital connections through employment or contract arrangements.

Historically, patient care at the hospital was administered mostly by – or under the direction of – community-based attending physicians, who did regular rounds and took call while also volunteering their time for medical staff activities.

Hospital-based medical practice was largely limited to those specialties defined by the need or advantage of having a fixed presence at the hospital, such as emergency medicine, anesthesiology, radiology and pathology.

Now, however, due to technological advances, the need for professional or institutional survival, economic impetus and personal lifestyle choices, more and more physicians are joining the medical staff as hospital employees or independent contractors. This phenomenon has manifested in the growing on-site presence of hospitalists, both in primary care specialties and in subspecialties, including neurohospitalist, OBGYN-hospitalist or pediatric hospitalist practices.

Additionally, with the ever-increasing emphasis on patient safety and quality care, hospitals are hiring full-time chief medical officers or salaried department chiefs to replace the historical model of the community-based senior medical staff member who volunteered part-time service as a director of medical affairs or of a department.

Consequences for medical staffs

This changing dynamic of the practice arrangements of physicians on hospital medical staffs has resulted in a number of issues and challenges for the medical staff as a “co-equal” partner with those responsible for carrying out the hospital’s institutional mission.

Here is a look at some of the major implications of these changes:

- Even outside of academic teaching institutions, physicians who have hospital connections through employment or contract arrangements chair many clinical departments or services.
- The medical executive committee may have a majority of these



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employed or contract physicians among its members.

- There is a decreased presence of community-based attending physicians on-site at the hospital, as these physicians must spend more time in their own offices to see patients and earn a living.
- We have seen a reduced influence of community-based physicians on the development of medical staff bylaws, rules and regulations, and policies, as they are able to devote only limited time to medical staff governance activities.
- There is a potential for cultural dichotomy and divided loyalties among medical staff members, and possible negative consequences for medical staff collegiality, cohesive decision-making and fair process in credentialing, peer review, corrective and disciplinary action, and hearings and appeals.
- There are greater challenges in re-credentialing medical staff members whose professional activities require less frequent on-site presence at the hospital, resulting in a diminished opportunity for credentialing committees to evaluate these members’ professional performance.
- Challenges in allocating call coverage responsibilities are increasing.
- We have seen a lessened connection or continuity for community-based physicians in the medical management of admitted patients.
- There is tighter hospital control over medical staff membership and privileges through employment contract termination provisions.

What to do?

These consequences of the changing mix of physician practice arrangements are playing out against the backdrop of federal Medicare and Medicaid and Joint Commission credentialing re-

quirements, and medical staff bylaws that could bear updating to reflect the changing scene.

There are a variety of things that physicians and hospitals can do to meet the challenges of the evolving medical staff.

- **Review and revise medical staff bylaws to provide strong support for an autonomous, self-governing medical staff.**

The medical staff can be accountable for quality care and patient safety only if its self-governance is supported by governing documents, including medical staff bylaws that, consistent with legal and accreditation requirements, recognize its self-governing role within the hospital.

In particular, the medical staff bylaws should contractually bind hospital leaders to respect the medical staff’s autonomous structure and its collaborative responsibilities in areas such as credentialing, privileging, peer review and oversight over clinical quality.

No bylaws should be rewritten without regard for applicable federal and state statutes and regulations, including the Massachusetts Board of Registration in Medicine Patient Care Assessment Regulations, Joint Commission standards (including newly-finalized standard MS.01.01.01, to be effective in March 2011), and policies and guidance from organized medicine.

- **Encourage an inclusive and shared culture among medical staff members from disparate practice settings.**

A fractious “us-versus-them” mentality not only disserves the overall institutional patient care mission of the hospital, but also it divides the focus of the medical staff’s objectives in protecting the interests of its members.

If hospital-employed physicians understand that they have a stake in the medical staff enterprise, they are

Continued on page 15

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Dealing with the changing dynamic of the medical staff

Continued from page 14

more likely to appreciate and support the legitimate concerns of their medical staff colleagues. A cohesive medical staff is best for physicians and hospital alike.

- **Elect strong, competent and reasonable medical staff officers.**

Regardless of their individual practice arrangements, medical staff members serve their own best interests by choosing officers who understand the importance of medical staff self-governance and autonomy, can stand

up for legitimate medical staff concerns, and are able to advance the medical staff's interests with hospital trustees and administrators through reasoned and cooperative discussion.

- **Address conflicts of interest fairly, impartially and objectively.**

Even though the hospital may have imposed a conflict of interest policy, it is also essential for the medical staff itself to have policies or mechanisms in place for identifying conflicting professional, economic or personal interests,

and for abstention/recusal of conflicted members from participation on panels that decide core matters of medical staff membership and privileges, such as credentialing, peer review and corrective action committees, professional practice evaluation and investigation of sentinel events.

Further, the medical staff bylaws should be structured to insure adequate community-based physician representation on such panels and on other governance bodies, including participation in conflict/dispute management processes.

- **Encourage free, open and reasoned communication among medical staff members and with hospital leaders.**

A repressive institutional culture will exacerbate division between community-based independent physicians and hospital physicians, hindering the advancement of quality patient care.

Both medical staff and hospital leaders should work to enhance open and respectful dialogue among the medical staff around quality of care and administrative policy. All parties are well served by honest and reasoned communication.

The 21st century medical staff will continue to evolve in character and composition, as physician practice arrangements undergo constant change in the health care marketplace. The medical staff's survival as a central and crucial player in the hospital's institutional mission will depend on its members' ability to meet the challenge with an enlightened and forthright perspective. **MMLR**

This article was first published in the May 2010 issue of the Massachusetts Medical Law Report.

The Physician's Corner

How to approach changes in medical staff rules

By Henry Tulgan, MD, FACP

When I first started practicing medicine, every morning the doctor's lounge seemed to be filled with a number of elderly practitioners – some in their 80s – who had just seen the few patients they were still caring for in the hospital, and enjoying their coffee and first cigar before going off to their offices.

Those offices were often "run" by a family member who served as receptionist, medical assistant and billing clerk. Malpractice insurance? Virtually none of them had it, because nobody sued their doctors.

How times have changed. So few octogenarians remain in practice, and those that are practicing have malpractice coverage and have all abandoned their cigars. Office practice is so much more sophisticated as well, mostly in groups with cadres of skilled practice extenders, such as physician assistants and nurse practitioners.

And as much as private practice has changed, medical staffs and hospital/physician relationships have changed even more.

When that older generation was so visible in the hospital, only pathologists, anesthesiologists and radiologists were employed by or had contractual relationships with the hospital's administration. Emergency physicians were the next to follow.

Medical staff bylaws were written and directed by community practitioners who served voluntarily, often on a rotating basis, as department chairs and in other leadership roles.

However, the modern hospital staff is dramatically different. These changes began with the academic medical centers but they have now reached smaller and specialty-oriented institutions as well.

A significant number of physicians are now either employed by hospitals or have contractual relationships with hospitals. In addition, there is an increasing number of salaried Chief Medical Officers and Chiefs of Clinical Services which, in turn, diminishes the influence of the remaining community practitioners.

These shifts are leading to changes in bylaws and other staff policies in which these physicians may have little or no voice, particularly with powerful hospital administrations controlling these physicians' employee contracts, which are written in a way that is favorable to the hospital.

Until recently, regulations from the Joint Commission and the Centers for Medicare and Medicaid Services (CMS) seemed to support bylaws that favored these newer arrangements, and both national and state medical organizations have spoken up for their members

to that end. The Joint Commission has issued revisions to its rules (MS.01.01.01) allowing an expansion of the roles and responsibilities of medical staffs to govern themselves, with the caveat that these changes still are to be ratified by each hospital's board of trustees.

Various experts and groups have suggested ways independent physicians can respond to the power that hospital administrators have gained by having so many physicians as employees. Joint Commission accredited hospitals need to be in compliance before March 31, 2011.

Suggestions include the development of Physician Services Organizations (PSOs) – which deal with physician practice structures, governance and operation, often in conjunction with the hospital administration – or investment in developing physician leaders.

Certainly, more than one model could work well. However, it is incumbent on medical staffs, both the remaining independent community practitioners and the employed ones, to stand up for their rights and concerns while working cordially with hospital administrators and trustees.

Issues that never existed in the past such as conflicts of interest and economic incentives in the contracts of employed staff members make rep-

resentation of non-employed members a necessity in leadership.

In this rapidly changing health care milieu, it is necessary for survival of medical staffs, administrators and trustees alike in all of our institutions, large or small, full-service or specialty, academic or not, to work together cordially.

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

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1. Hospitals are hiring full-time chief medical officers or salaried department chiefs to replace the historical model of the community-based senior medical staff due to the increased focus on patient safety and quality care.

- a. True
 b. False

2. The Joint Commission has recently revised standards (MS.01.01.01) to allow changes in medical staff bylaws that are scheduled to go into effect in March 2011.

- a. True
 b. False

3. In spite of the changing dynamic of medical staffs, challenges in allocating call coverage responsibilities are decreasing.

- a. True
 b. False

4. Physician Service Organizations could be developed to implement the recent changes in requirements for medical staff bylaws.

- a. True
 b. False

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Board of Medicine releases new prescribing guidelines

Continued from page 1

of the quality initiative we've had as part of our goals in terms of patient advocacy and outcomes," she says.

At the same time, Coombs, a Weymouth anesthesiologist, says she hopes the Board will give physicians – many of whom may be unaware of the revisions – time to become educated about and acclimated to the new guidelines before they intensify their enforcement efforts.

Handy tool

William M. Mandell, a health care attorney at Pierce & Mandell in Boston, says that the guidelines are useful because they pull together in one place the prescribing rules of the road for physicians.

"The Board's authority to investigate and discipline doctors more often than not is a question of other legal sources or of Board policy that's not always in a statute or a codified regulation," he says. "So they're doing an important service to the physician community by putting it together."

In terms of specific provisions, the major changes address:

• Supervision of mid-level practitioners

The guidelines provide, for the first time, a comprehensive description of when a non-physician can prescribe medication independently, under a physician's supervision. Among other things, physicians must draft guidelines for nurse practitioners and physician assistants under their supervision to follow. And the supervising physician must be trained, board-certified and have admitting privileges in the non-physician's area of practice.

While the rules themselves aren't new, says Aims, they didn't appear in the previous guidelines because mid-level practitioners weren't allowed to prescribe in 2001.

The benefit of this provision, says Mandell, "is clearly to give medical practices assurance that if there was ever any doubt or concern, the Board is blessing physicians to pursue broader roles for physician extenders, physician assistants and advanced practice nurses so they can operate and move toward a medical home model with a team of clinicians."

David Harlow, a Newton lawyer and health care consultant, noted a provision dealing with collaborative practice agreements under which pharmacists can, in certain situations, "initiate, monitor, modify and discontinue" a patient's drug therapy.

"While a pharmacist won't be out having an independent practice and subscribing medication, there will be some opportunities for pharmacists to be providing information and oversight in certain limited settings," he says. "This is a worthwhile thing to do, particularly as we continue facing a physician shortage in primary care."

• Prescribing Schedule II substances and prescribing for treatment of pain

"This is an area where prescribing can be

particularly challenging," says Aims. "Schedule II substances are challenging by nature, trying to determine who's a drug seeker, who has legitimate pain and who's abusing drugs."

Accordingly, the new guidelines include a more detailed section on issuing multiple prescriptions for Schedule II drugs, clarifying that any such prescription is only valid for 30 days.

"The expectation is if you're treating someone for chronic pain, you'll be in regular con-

tact with that patient to monitor [his or her] progress," says Aims.

Similarly, says Mandell, the guidelines lay out specific limitations on office treatment of opioid addiction. In order to run a narcotic-treatment program, physicians now have to be registered with the Drug Enforcement Agency and licensed by the Massachusetts Department of Public Health. Similarly, if it's a doctor's office setting, the DEA needs to pro-

vide a waiver.

"This has been a big area for potential abuse and there have been a lot of cases by the Board against doctors who've crossed the boundaries on treatment," says Mandell. "[These provisions] make things tougher for independent physician practices, but, again do less to make new law than to pull together different strands of laws and regulations already out there."

• Gifts from the pharmaceutical industry

The Legislature enacted a law last year barring most gifts from drug and device marketers to physicians. But the law targets the marketers rather than the recipients of the gifts, and subjects the marketers to penalties.

As a result, says Aims, many physicians – especially solo practitioners and non-MMS members who may be more isolated from awareness initiatives – don't realize that they're also expected to refrain from accepting gifts.

Accordingly, the Board has referenced the new law – as well as the American Medical Association's policy on inappropriate gifts – in the guidelines to serve as a reminder.

"By doing so, the Board is making it abundantly clear that it has jurisdiction to police licensees and hold them accountable for any violations of the Massachusetts law, even though the law itself regulates drug and device companies," says Mandell. "The Board, in essence, is reserving its right to investigate and sanction physicians."

• Electronic prescribing

David Szabo, a health care lawyer at Edwards, Angell, Palmer & Dodge in Boston, says that if there's one area where the guidelines fall short, it's in the area of e-prescribing Schedule II through V controlled substances.

As Szabo explains, a new federal DEA rule provides a pathway for doctors to electronically prescribe such medications. For Massachusetts to get the benefit of this new rule, DPH needs to change its own prescribing regulations as well.

However, Szabo is disappointed that the guidelines merely mention that there's a DEA rule, that it was released on an interim basis, and that it's subject to review by Congress, without indicating its own position on the issue.

"I think [the Board] should have explicitly said that once the federal regulation goes into effect and the DPH amends its rules, then physicians can lawfully and electronically prescribe controlled substances," he says.

Instead, the Board has sent an unclear message, says Szabo.

"I don't know whether it means the Board is going to engage in further review of the matter or whether the absence of saying anything about it means it's OK," he says. "I think it just creates a little cloud of uncertainty in an unnecessary manner." MMLR

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



“By uniting [the piecemeal policy changes over the past decade] in a single document that we hope is more user-friendly and flows more logically, it'll make it easier for physicians to understand their responsibilities and the Board's expectations.”

— Russell Aims, Board of Registration in Medicine

Payment reform and delivery system reorganization are coming

Continued from page 3

A group led by Children's Hospital Boston was one of only four SHARP grant recipients in the country. Dr. Isaac Kohane discussed the grant program, which is intended to view the iPhone as a model for health IT: "We need substitutability more than interoperability. Clinicians should be able to plug new applications into their electronic health record systems without" having to replace entire computer systems.

While the technology transformation is exciting, payment reform is coming and will be the hardest challenge, but also the most important and foundational, said Campbell.

The state legislature's payment reform legislation will build upon the Special Commission on the Health Care Payment System rec-

ommendations. In July 2009, this Commission unanimously recommended global payments within five years.

Rep. Stanley candidly acknowledged that it will be difficult for the legislature to enact payment reform in an election year when the legislative session ends on July 31.

"We need you to encourage your legislators to support the payment reform and delivery system transformation," she said.

"We need to change the culture in our state, and to engage consumers in cost control," Rep. Stanley added. "We've done the easy part (enacting universal coverage), but unless we do the hard part right (payment reform), we'll endanger universal access. We don't have to work everything out before starting this journey; we have to get started." MMLR



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