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Inside: 2001 reader survey

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Advice-of-counsel defense not as useful as you might think, or hope, in civil cases

Look to counsel for advice, don't ignore responsibilities

Risk managers rely on legal counsel to provide important advice, but there is a real danger in relying upon it too much. When push comes to shove, it probably isn't going to do you much good to say, "Our attorney said it was OK."

The technical term for that is the advice-of-counsel defense, and many risk managers have thought about using it at some point. The advice-of-counsel defense can be used successfully in some situations, but some sources caution that risk managers may think it more useful than it really is. It is a serious mistake to rely too heavily on an attorney's opinion instead of exercising your own good judgment as a risk manager, says **Grena Porto**, RN, ARM, DFASHRM, director of clinical risk management and loss prevention services at VHA Inc. in Berwyn, PA, and past president of the American Society for Healthcare Risk Management.

"I still very much advocate going to legal counsel for many issues, and you have to seriously consider their advice; but you should consider them a valuable resource and not necessarily the final word for everything," Porto says. "A court's not going to let you off the hook because you asked a lawyer first."

Attorneys are likely to tell you the same thing, and they worry risk managers have too much faith in the advice-of-counsel defense. **John Boese**, JD, an attorney with Fried Frank in Washington, DC, cautions risk managers that the advice-of-counsel defense rarely is useful.

Boese says many defendants in civil False Claims Act (FCA) cases contend they should not be liable

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for punitive damages and penalties if they sought and followed the advice of legal counsel. That defense is "virtually never accepted by the court," he says.

Courts will expect risk managers, and the health care administration as a whole, to exercise good judgment and not rely excessively on an attorney's opinion, Boese says. A consultation with an attorney is never going to be an all-purpose, get-out-of-jail-free card, he warns.

"People just rely too much on this defense, even if they never have to use it," he says. "They keep it in the back of their mind as the big defense they'll put out if they have to, but they're going to be disappointed at how poorly it works."

Don't abdicate your responsibilities

Porto says there are plenty of occasions in which risk managers should consult legal counsel for advice — and you should listen carefully to what they have to say. But Porto cautions risk managers can let themselves get too dependent on that process and see it as a way to just defer making a difficult decision. That's not good risk management, she says.

"You have to keep in mind that the attorney's opinion is only one factor that goes into the mix," she says. "A lot of people — not just risk managers, but also other hospital administrators — tend to stop when an attorney speaks and treat it like the word of God. But even attorneys will tell you it's just their opinion."

Risk managers must remember they have a responsibility that is equally important as the attorney's, even though they may work closely together to hammer out a decision. It is inevitable the risk manager sometimes will have to make a decision that the attorney disagrees with, Porto says. A particular risk is posed by consulting with the provider's *defense* attorneys for general counsel questions. She points out that different attorneys will have their own perspectives that must be factored into the risk manager's decision.

"A defense attorney will look entirely at mitigating damages and limiting liability. They're not going to look at your other responsibilities, like fiduciary obligations and the facility's public image," Porto says. She cites the example of a risk manager who wants to formally apologize to a patient who has been harmed. If you ask the defense attorney about that possibility, he or she is likely to say no. Even though an apology is not an admission of guilt, a defense

attorney will lean toward playing it safe.

In another example, Porto questions how an attorney would respond when a risk manager wants to disclose to a patient that something went wrong during surgery. The defense attorney, and maybe even other legal counsel, is likely to say you shouldn't tell the patient because you might get sued.

"That does not relieve you of your obligation to the patient," she says. "You are going to be held to the standards of your profession, and health care risk managers certainly have a code of ethics and other standards to follow."

Case shows rare instance of appropriate use

Boese tells *Healthcare Risk Management* that the advice-of-counsel defense can be used successfully, but only in a narrow area of court actions. Courts will be more receptive to the defense when the issue at hand is extremely complex and beyond the assessment of the typical hospital administrator.

"It's no good in cases where things are pretty clear, like coding questions. Everyone is going to reach the same conclusion once the facts are in," he says. "But it's going to look better in cases where lawyers and lawyers' advice are critical for whether to proceed with what you're doing. That's when the advice-of-counsel defense will make more sense, but it's still not something you want to pin all your hopes on."

Boese notes the advice-of-counsel defense requires the defendant to waive attorney-client privilege, which opens up a whole can of worms for providers. He calls one recent case "unusual and important" because it shows the specific cases in which advice-of-counsel might be a good defense. In that case, a physician succeeded in having a court dismiss with prejudice false claims act claims related to allegedly illegal kickbacks *(United States ex rel. Bidani v. Lewis,* No. 97 C 6502, 2001 WL 32868 [N.D. Ill. Jan. 12, 2001]). The relator in that case alleged the defendant received illegal kickbacks by referring dialysis patients to supply companies owned and controlled by the defendant. In a previous decision, the court concluded the relator had stated an actionable FCA claim based on alleged violations of the Anti-Kickback Act.

Evidence was presented in a motion for summary judgment, demonstrating the defendants (the physician and two corporate entities controlled by the physician) sought and relied on the advice of counsel — who provided testimony to the court — as to the legality of the disputed arrangements. The court determined a defendant asserting the advice of counsel defense must demonstrate that "before taking action, the defendant sought in good faith the advice of an attorney he believed to be competent for the purpose of securing advice on the lawfulness of his possible future conduct, made full and accurate report to counsel of all material facts which the defendant knew, and acted strictly in accordance with the advice of the attorney who had been given a full report."

Boese says the court considered client memoranda and other attorney-client communications regarding the ownership relationship, concluding the defendants sought and followed the advice of their attorneys regarding the legality of their conduct. The court noted the defendants apparently did not hide any relevant facts from counsel, that counsel kept defendants advised of changes in the applicable statutes and regulations, and that the defendants changed their conduct accordingly.

Counsel testified for defense

The court also considered a variety of government documents, including federal audit reports, relating to the common ownership of dialysis facilities and clinics. Although the court never decided whether the applicable statutes and regulations had been violated, it stated the relator has the burden to show (by a preponderance of the evidence, under the FCA) that defendants knew their conduct violated applicable regulations in order to satisfy the act's scienter requirement.

Boese says the court held that the only reasonable inference that could be drawn from the evidence was that the defendants had no actual knowledge that the common ownership arrangement was improper. The court thus held that the relator could not demonstrate that defendants knowingly presented or caused false Medicare claims to be presented to the government, and granted defendants' summary judgment motion with prejudice.

The case was unusual, Boese says. He notes that it is extremely uncommon for the provider's counsel to actually testify, but in this case, the provider's attorney essentially told the court "this is a very confused area of law, and I told them what they were doing was OK." The FCA also is unusual in that it requires proof the defendant knew or should have known the action was prohibited.

"If you had asked me before this case how many times the advice-of-counsel defense had been successful, I would have said, 'None,'" Boese says. "Now I'd say, 'One.'" ■

Major review set for privacy regs

Bush to sort through Clinton policy — again

The controversial privacy regulations bestowed upon the health care industry as a parting gift by the Clinton administration may not affect providers as much as or as quickly as it first seemed. The Bush administration has made it clear the rules may be a bad idea, and federal officials are taking moves to slow down the implementation while they consider a wholesale change or revocation of the rules.

Tommy G. Thompson, the new secretary of Health and Human Services (HHS), announced recently he was delaying the implementation of the privacy rules and considering whether to stop the implementation altogether. The rules were scheduled to take effect Feb. 26, but Thompson postponed the effective date to April 14. Providers still will have two years to come into compliance, as originally outlined.

Thompson's action came after much lobbying from the health care industry. Providers had appealed to Thompson and others in the Bush administration, and groups representing patients and the health care industry both called for changes before the Senate's Health, Education, Labor, and Pensions Committee. Thirty-nine industry groups wrote Thompson, urging him to delay the Feb. 26 effective date of the rules. Representatives from several of those groups told the committee that, as written, the rules are unworkable.

Thompson announced the delay in implementing the rule in a speech to the American Association of Health Plans, a trade group for health maintenance organizations. Thompson said the implementation was being delayed partly because of the Bush administration's concerns about how the rule would affect providers, but also because they feel the Clinton administration mishandled the rule-making process. Thompson said the rules were published in the *Federal Register* on Dec. 28, 2000, but the Clinton administration never sent them to Congress for a 60-day review, as required by a 1996 law. That law, the Congressional Review Act, requires a 60-day period before any major new rule can take effect.

G. Richard Smith, MD, testified before the Senate committee on behalf of the Association of American Medical Colleges. He said "the rule is overreaching; that it will be much more costly and burdensome than the rule's authors wish us to believe, and will create an expensive new 'privacy bureaucracy' that, absent sources of new funding nowhere yet identified, represents a substantial unfunded mandate; that it cannot be implemented effectively nationwide within the two-year compliance window specified; and that the inability of the rule to pre-empt state laws will prove to be increasingly problematic and burdensome, in an era in which individual mobility, interstate health care delivery, payment and operations, and interstate research are all commonplace."

The rules are costly

Critics argued the rules are likely to be more expensive than many entities will be able to bear and likely to cost far more than the $17.6 billion estimated by HHS. They also said the final version of the rule includes a new requirement for individual consent for treatment, payment, and other routine uses of information that could prove problematic.

One example was the concerns of pharmacists about getting patient consent for prescriptions that are called or faxed to pharmacies and picked up by the patient's relative.

Health care industry officials testified about their concern that stronger state privacy laws would remain in place. One critic asked about a situation in which a patient lives in one state, works in another, and receives care in a third. Would that situation be governed by state law where the policy is written, where the patient lives, or where the care is provided?

The Senate also heard from some supporters of the rules who want them strengthened. Among other suggested changes, they asked the committee to create a "private right of action" to allow those whose information is wrongly disclosed to sue for damages, and to close what some call a loophole in the regulations allowing the use of personal information for marketing and fundraising.

The American Psychiatric Association (APA) submitted this testimony: "The APA is particularly

concerned about the need for sensitivity with psychiatric patients' names. Commercial fundraisers should not be allowed to take advantage of patients, especially those with mental illness." ■

Reader Question

Be a privacy officer only if you have time

Question: When we implement the new federal privacy rules, who should be the privacy official who the rules say must oversee the implementation and ensure patient privacy is protected? I'm sure our administrators will say that's another duty for the risk manager to assume.

Answer: You're not alone. A great many risk managers are bracing for the moment when they have to assume yet another role, says **Gregory J. Naclerio**, JD, partner and co-chair of health care practice at Ruskin Moscou in Mineola, NY. Naclerio has helped many institutions set up corporate compliance programs, and he notes many risk managers took on the duty of corporate compliance officer a year or so ago.

"I was at a meeting of compliance officers yesterday, and the scuttlebutt is that hospitals are going to make them privacy officers now," Naclerio says. "I can tell you it's not going to work."

The problem is that risk managers already are overburdened and they have to draw the line somewhere, he says. If the risk manager is not already the compliance officer and not already saddled with some other type of duty, it is possible — but still not advisable — to take on the role of privacy officer. Recent trends in the health care industry make it unlikely that there are many risk managers who still do only pure risk management and haven't been given more duties, Naclerio says.

With every additional task, the risk manager's performance is likely to suffer, he says. Most risk managers/compliance officers already are not doing a sufficient job of monitoring corporate compliance, Naclerio says.

"People are already wearing two or three hats, and the compliance hat always is on the lowest rung. If they have time, they get around to compliance," Naclerio says. "If you add privacy officer to that, it would be on the bottom rung, or maybe you'd shove compliance down even further. That's not good."

Risk managers should resist any suggestion that they can take on the privacy officer role and do it effectively, he says. At some point, he says, health care organizations will have to start hiring more people to take on these new roles mandated by the government, instead of automatically turning to the risk manager.

"There has to be a limit somewhere to how many tasks a person is charged with," Naclerio says. "It's one thing to say that this person has this responsibility and this responsibility and this one too, but that's not going to matter if the person can't actually do those jobs. You have it all spelled out on paper, but the government's going to expect that the person actually does the job." ■

IOM says safety rules need major overhaul

The second report from the Institute of Medicine (IOM) of the National Academies paints a grim picture, saying the nation's health care industry has foundered in its ability to provide safe, high-quality care consistently to all Americans. "Reorganization and reform are urgently needed to fix what is now a disjointed and inefficient system," the report states.

To spur an overhaul, Congress should create an innovation fund of $1 billion for use during the next three to five years to help subsidize promising projects and communicate the need for rapid and significant change throughout the health system, the report adds. Just as a solid commitment of public funds and other resources supported the ultimately successful mapping of the human genome, a similar commitment is needed to redesign the health care delivery system so all Americans can benefit, says **William Richardson**, chair of the committee that wrote the report and president of the W.K. Kellogg Foundation in Battle Creek, MI.

"Americans should be able to count on receiving care that uses the best scientific knowledge to meet their needs, but there is strong evidence that this frequently is not the case," Richardson says. "The system is failing because it is poorly designed. For even the most common conditions, such as breast cancer and diabetes, there are very few programs

that use multidisciplinary teams to provide comprehensive services to patients. For too many patients, the health care system is a maze, and many do not receive the services from which they would likely benefit."

Chronic conditions need more attention

The report says clinicians, health care organizations, and purchasers — companies or groups that compensate health care providers for delivering services to patients — should focus on improving care for common, chronic conditions such as heart disease, diabetes, and asthma that are now the leading causes of illness in the United States and consume a substantial portion of health care resources. Those ailments typically require care involving a variety of clinicians and health care settings over extended periods of time. But Richardson says physician groups, hospitals, and health care organizations work so independently of one another that they frequently provide care without the benefit of complete information about patients' conditions, medical histories, or treatment received in other settings.

The committee's previous report, *To Err Is Human: Building a Safer Health System*, found that more people die from medical mistakes each year than from highway accidents, breast cancer, or AIDS. But Richardson says findings in that report amounted to only the tip of the iceberg in the larger story about quality care. The IOM calls America's health care system "a tangled, highly fragmented web that often wastes resources by providing unnecessary services and duplicating efforts, leaving unaccountable gaps in care and failing to build on the strengths of all health professionals."

The report calls for immediate action to improve care over the next decade and offers a comprehensive strategy to do so. The report envisions a revamped system that not only is centered on the needs, preferences, and values of patients, but also encourages teamwork among health care workers and makes much greater use of information technology. The IOM committee suggests more emphasis on electronic records, communicating with patients via e-mail, and automated medication order entry systems that can reduce errors in prescribing and dosing drugs. However, the report recognizes that many policy, payment, and legal issues would have to be resolved before much headway could be made.

To initiate across-the-board reform, the IOM says the federal Agency for Healthcare Research and Quality should identify 15 or more common health conditions, most of them chronic. Then health care professionals, hospitals, health plans, and purchasers should develop strategies and action plans to improve care for each of those priority conditions over a five-year period. The report also calls on the U.S. Department of Health and Human Services (HHS) to monitor and track quality improvements in six key areas: safety, effectiveness, responsiveness to patients, timeliness, efficiency, and equity. The HHS secretary should report annually to Congress and the president on progress made in those areas, the report says.

Quality equals safety

The study was sponsored by the IOM, the National Research Council, the Robert Wood Johnson Foundation, the California Health Care Foundation, the Commonwealth Fund, and HHS. The National Patient Safety Foundation (NPSF) welcomed the second report, saying it emphasizes how important it is to make care safer for patients.

"Harming patients is a critical indicator that quality improvements are needed. You can't have a quality system that is not safe," says **Joanne Turnbull**, PhD, executive director of the NPSF. "To create safe systems, we need multidisciplinary teams that work together to identify and implement solutions. We need a commitment to continuous learning and continuous training, and we need to more quickly move from theories and concepts to applications and system improvements."

Turnbull says the NPSF has involved patients and family members who have experienced medical errors in their efforts to improve health care safety.

"We've learned a tremendous amount about what they expect and need as they deal with so many unfortunate consequences," she says. "We must value patients' perspectives, and adopt better principles of patient-centered care if we're going to make care safer."

Earlier this year, the NPSF developed its own "Statement of Principle" to encourage better communication with patients. The statement was mailed to nearly every hospital CEO and board trustee across the country. It urges health care professionals to be open and honest in their communication with patients and families, and to share information about errors in a timely and proactive manner. ■

Costs soar; some PA OBs are calling it quits

Pennsylvania obstetricians, reeling from some of the highest liability insurance premiums in the country, are leaving their practices in record numbers. Many are retiring early, choosing to practice in neighboring states, or giving up the delivery of babies altogether as they try to grapple with the nearly impossible financial burden of soaring malpractice insurance costs.

And they're not the only ones suffering from the situation. According to a recent report from the Pennsylvania Medical Society, the state's dwindling number of obstetricians is having a direct impact on the care expectant mothers receive. While the situation hasn't reached epidemic proportions yet, the report says it will soon if state medical liability laws aren't changed to address frivolous lawsuits and other abuses of the medical liability system, according to **Michelle Vichnin**, MD, an OB/GYN from Reading, PA, and member of the Council on Policy and Governmental Affairs of the Pennsylvania Medical Society.

"The situation is out of control and, unless changes are made, could lead to a rationing of medical care in Pennsylvania," Vichnin says. "Although malpractice laws are intended to protect patients, unfortunately there have been many unfounded complaints and a resulting financial strain on all Pennsylvania obstetricians who must share in escalating insurance costs."

The society, which has advocated for patients and their physicians for more than 150 years, is aggressively urging the state legislature to reform current laws it says jeopardize the ability to sufficiently provide necessary medical care for expectant women in Pennsylvania.

Gerard Klinzing, MD, chairman of the department of family practice at Main Line Health Hospitals in suburban Philadelphia, says, "Patients will continue to lose access to care if we don't fix Pennsylvania's medical liability system. In the last year, the number of our obstetricians has declined by more than 10% due primarily to rising liability insurance costs."

Another Pennsylvania medical practice devoted solely to obstetrics and gynecology, cited in the report, says its premium for private malpractice insurance nearly tripled this year. On the verge of bankruptcy, the practice decided that two of its seven physicians would stop delivering babies just to cut its nearly $1 million premium in half. Statewide, the Pennsylvania Medical Society has received numerous reports from obstetricians who have stopped practicing or given up high-risk procedures. A reduction in obstetricians increases patient load for remaining doctors who already have practices bursting at the seams. In some cases, obstetrical patients become a priority while other women wait for necessary gynecologic care or preventive exams.

"The situation is as frustrating for doctors as it is for patients," Vichnin says. "Doctors must be able to spend a reasonable amount of time in the examining room in order to develop a relationship that leads to better understanding and healing of the patient."

Recruiting new physicians to fill the gap isn't necessarily the solution either. Young doctors often are unwilling to practice in Pennsylvania because of the malpractice environment. New obstetricians generally look to practice in states where malpractice liability laws already have been reformed.

"Young doctors typically begin their careers carrying more than $100,000 in debt from educational and training costs," Klinzing says. "They sometimes find it economically impossible to pay off student loans and also purchase liability insurance in Pennsylvania."

Over the past two years, 66% of Pennsylvania physicians involved in recruitment have had difficulty persuading new doctors to practice in the commonwealth, according to the Pennsylvania Medical Society. ■

Doctors on-line often, and are wary of privacy

New research shows more physicians are going on-line from home, their personal office areas, and their clinical work areas, and many of them are concerned about violating patient privacy.

Physicians' staff also are using the Internet more often for both clinical and administrative work. Most physicians now go on-line on a daily basis, and two out of every five doctors work in practices that have web sites, up from just over a quarter 13 months earlier. Those are some of the findings of a new nationwide Harris Interactive survey of 834 physicians.

The survey was conducted between Jan. 3 and Feb. 7, 2001. The study found well over half (55%) of all practicing physicians use e-mail to communicate with professional colleagues, and a third (34%) use e-mail to communicate with their support staff. However, only 13% of all doctors communicate with any of their patients via e-mail.

Internet, web site, and e-mail usage have all increased significantly, but not dramatically, since December 1999, when the previous "Computing in the Physicians' Practice" survey was conducted. The proportion of all practicing physicians using the Internet has grown in the clinical work area (from 34% to 40%), in their personal offices (from 51% to 56%) and at home (from 83% to 87%). Only 7% of physicians are not on-line anywhere, compared to 11% in 1999. Forty-two percent of all physicians work in practices with web sites, up from 29% in 1999.

Only a few physicians are sending clinical information about individual patients via e-mail. However, the survey respondents indicated this number would rapidly increase if medical records' privacy were guaranteed.

More doctors are communicating by e-mail with both professional colleagues (up from 51% to 55%) and support staff (up from 25% to 34%). Only 36% of physicians are not using e-mail to communicate with staff, colleagues, patients, or third-party payers, compared to 42% in 1999.

Only a few physicians are sending clinical information about individual patients via e-mail. However, the survey respondents indicated this number would rapidly increase if medical records' privacy were guaranteed. Only 6% of physicians regularly use e-mail to send clinical information about individual patients (such as consultations with colleagues or patients, or ordering prescriptions) and are not inhibited about concerns about privacy and security. Another small minority (8%) uses e-mail to send clinical information, but "would do so even more if security and privacy were fully guaranteed."

Therefore, in total, only one in seven doctors (14%) is using e-mail to send any patient-specific clinical information. Many more (39%) do not, but say they would do so "if the security and privacy of e-mails were guaranteed." However, even if security and privacy were nonissues, fully 40% of physicians say they would not send clinical information by e-mail. ■

Medication delivery gets a safety boost

An innovative program for increasing the safety of medication delivery is being launched by the Health Care Improvement Foundation (HCIF), an affiliate of the Delaware Valley Healthcare Council (DVHC).

In what local leaders envision as a model for hospitals across the country, HCIF will assist more than 70 southeastern Pennsylvania hospitals with the tools to implement 16 safety action steps designed to further improve patient safety. To create the Regional Medication Safety Program for Hospitals, HCIF has partnered with two nationally recognized leaders in patient safety, the Institute for Safe Medication Practices (ISMP), located in Huntingdon Valley, PA, and ECRI, headquartered in Plymouth Meeting, PA. **Andrew Wigglesworth**, president of DVHC, says the partnership is a unique effort to improve patient safety. He also serves as president and CEO of HCIF.

"We believe this is the first time that all the hospitals in a major metropolitan area are teaming up to collectively work on enhancing medication safety," Wigglesworth says. "Given the tremendous fiscal pressure that hospitals are under these days, this program will not only provide additional support, in terms of expertise, educational services, and technology assessment, to promote the rapid and efficient implementation of safe medication practices across the region, but will also help institutions target scarce resources."

Total cost: Unknown

Over the past year, the DVHC has renamed its affiliated foundation and gave it a new mission, with the HCIF now focusing on supporting programs that enhance patient safety at hospitals throughout the region. The foundation's first initiative, the Regional Medication Safety Program for Hospitals, has a projected budget of $1.4 million, which will be utilized in the production and implementation of the tools and support designed to assist area institutions.

While a majority of the funding for the program is being sought from philanthropic foundations

and corporations, hospitals and health systems in the region are contributing $500,000 to launch the effort.

Mark Bruley, a vice president of ECRI, says it is difficult to estimate the total regionwide cost of implementing the 16 medication safety action objectives, as there is considerable variation in the individual safety initiatives currently in place at hospitals.

"For example, the cost of implementing computerized prescriber order entry systems at an individual hospital could range from $2 million to more than $10 million, depending on the size and complexity of the institution," Bruley says.

Richard Centafont, program director of the HCIF Regional Medication Safety Program for Hospitals, says the hospitals appreciate the expertise being put at their disposal. He notes that the creation of the program ensures they have the tools needed to successfully incorporate the 16 safety objectives into their organizational structures.

The role of the program

The two-year program will place a major emphasis on providing tools designed to enhance existing communication mechanisms and ensure all members of the health care delivery team are aware of critical medical information for every patient. Under the program, each institution will be asked to appoint a health professional in the new role of medication safety officer, who would help coordinate and guide a hospitalwide medication safety committee at each institution.

"Innovation and commitment to patient safety have always been hallmarks of our region's hospitals," Wigglesworth says. "By enabling hospitals to further strengthen their systems and processes, as well as supporting these efforts with tools and services, we will continue to improve already existing safe medication practices, increasing patient safety and overall health care outcomes at hospitals throughout the Delaware Valley."

HCIF is a nonprofit foundation affiliated with the DVHC. Its mission is to support innovative efforts to improve health services as well as enhance public trust and confidence in the region's health care delivery system through the promotion of best practices in community health and patient safety in the Delaware Valley. DVHC is a membership association representing more than 150 health care organizations in Pennsylvania, southern New Jersey, and northern Delaware. Its mission is to assist member organizations to improve the health status of their communities and to exercise leadership in the appropriate restructuring of the regional health care delivery system through advocacy, information, and education in the public interest. ■

Leading medical schools agree on new guidelines

Stressing the protection of research subjects supercedes any other concerns, the leaders of eight of the nation's top medical schools and another six nationally prominent leaders in academic medicine have drafted a set of guidelines that would strengthen most research institutions' policies for dealing with financial conflicts of interest that can arise from collaborations between faculty and industry.

Harvard Medical School dean **Joseph Martin**, MD, convened the group. He says it is impossible to avoid collaborations between medical school faculty and outside industry, but the guidelines can reduce the risk of improper influences.

"While academic-industry collaborations are essential if patients are to benefit from the current biomedical revolution, the integrity of those relationships must be monitored by policies that are clearer and more stringent than is the norm today," Martin says.

Filling in the gaps

The group's recommendations address inconsistencies and gaps in policies described in a series of four articles in the Nov. 1, 2000, *Journal of the American Medical Association* and the Nov. 30, 2000, *New England Journal of Medicine*. The group met recently in Washington, DC, to review the articles and discuss possible improvements in the system. Guidelines developed by the group were submitted to the Association of American Medical Colleges, which has formed a committee to review financial conflicts-of-interest policies for medical schools and teaching hospitals nationally.

Martin says the proposals are designed to guide individual institutions as they review their own conflict-of-interest policies, and were drafted with an eye to refining some of the weaknesses and gaps cited in the journal articles. The group recommends these actions:

• Require disclosure of financial interests to the institutional review boards that approve clinical research trials, something only around 1% of institutions do now.

• Apply required disclosure of financial ties to anyone involved in research — faculty, students, and staff — and require that disclosure should be both on a set periodic basis as well as in real time if their situation changes.

• Consider a higher standard for clinical research than for basic laboratory research.

The guidelines state: "Individuals directly involved in the conduct, design, or reporting of research involving human subjects should not have more than a clearly defined minimal personal financial interest in a company that sponsors the research or owns the technology being studied."

The guidelines also define financial interests that should be disclosed to include any fees, honoraria, or gifts associated with consulting or lectures, equity including stock options, and payments for directorships or executive roles. To make an institution's policy as specific as possible, the guidelines suggest that key terms, such as "family" be clearly defined and that there be a clear delineation of any allowable financial interest, such as mutual funds.

For research published in medical journals, the group recommends the journals require disclosure when the article is submitted, something only 7% of institutions do now. The group also encourages all biomedical science journals to require and publish disclosure of financial interests, something only 43% do now.

Martin says the guidelines were developed after much national debate on the topic, sparked by Harvard Medical School's announcement that it would retain its strict conflict policies. ■

Could intensivists save thousands of lives?

Physicians specializing in intensive care, known as intensivists, could save thousands of lives each year if only hospitals would hire more of them for intensive care units (ICUs), according to a presentation at the recent meeting of the Society of Critical Care Medicine in San Francisco.

John Hoyt, MD, an intensivist at St. Francis Hospital in Pittsburgh and chair of the new foundation, announced the group would be spearheading an effort to change the way ICUs are organized. Only one out of seven of the 5,000 ICUs in the United States are led by an intensivist, he says.

Intensivists gained more attention when the Leapfrog Group, a California consortium of health care purchasers, called for more of them as a way to improve patient safety. The Leapfrog Group has estimated that some 58,000 lives could be saved annually by staffing ICUs with specialists, computerizing the filling of prescriptions and referring complex operations to high-volume medical centers.

Most hospitals, 85%, employ a full-time intensive care nurse to run the unit, he says, with physicians in each specialty treating individual patients. But Hoyt says recent studies indicate patient care can be improved by employing a specialized intensive care team led by a full-time physician, and including a dedicated intensive care nurse, pharmacist, and respiratory therapist. That dedicated team also can reduce errors and decrease deaths, he says.

Hoyt says the group wants to increase the number of ICUs led by an intensivist to 50% in the next five years. The group plans to raise $1.5 million to educate the public about the need for intensivists, conduct research into the improved safety of having an intensive care team, and convince medical professionals to train for this specialty. ■

Doctors suspended for operating on wrong side

A New York hospital suspended two doctors recently, charging they operated on the wrong side of a man's brain because the CT scan was placed backward on a viewing screen. Another surgeon accused of wrong-site surgery received what the state health department calls too light a sentence.

The Long Island College Hospital in Brooklyn and the New York State Health Department both report they are investigating the brain surgery incident. The patient survived the experience, undergoing another procedure the following day to remove a potentially fatal blood clot.

The hospital released a statement: "Well-established hospital policies were clearly violated. The incident was reported promptly to the appropriate

regulatory agencies, and the hospital will cooperate fully with their investigation."

The hospital reports Rene Kotzen, MD, and Mike Chou, MD, were suspended the day after the alleged mix-up.

Appeal is planned

In another New York case, the state health department announced recently it will "vigorously" appeal the failure by a hearing committee for the New York State Board for Professional Medical Conduct to revoke the medical license of Ehud Arbit, MD, a neurosurgeon at Staten Island University Hospital. The committee found that he committed gross misconduct.

"The State Health Department vehemently disagrees with the hearing committee's decision, and will aggressively appeal the penalty to the administrative review board," according to a statement released by State Health Commissioner **Antonia Novello**, MD, MPH, DrPH. "This, the second disciplinary action against Dr. Arbit in only four years for an egregious act of medical negligence, demonstrates convincingly why he must get no more second chances. Dr. Arbit has shown a history and pattern of careless practice that has placed patients at unacceptable risk and which warrants nothing less than the revocation of his license."

The committee members determined Arbit was guilty of gross negligence for an act of misconduct they termed "egregious," but ordered that his medical license merely be suspended, with such suspension limited to the time he has already spent out of practice since signing an Order of Conditions with the state health department in February 2000. The committee also ordered Arbit

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be placed on probation for three years. The terms of probation require Dr. Arbit to limit his practice of surgery to a health care facility licensed under Article 28 of New York State Public Health Law, to have a practice monitor during his period of probation, and to complete a course in medical record keeping.

"The duty of the Health Department is to protect patients. The terms of probation determined by the committee are in no way sufficient to protect patients in light of Dr. Arbit's demonstrated inability to learn from his past mistakes," Novello says. "This department must, and will, do whatever is necessary to protect patients from doctors who are repeatedly and flagrantly careless and inattentive in the practice of medicine."

Details of misconduct

The health department says the most recent misconduct finding stemmed from an operation in which Arbit operated on the wrong part of a patient's spine. As a result, the patient had to undergo another surgery. The hearing committee members called Arbit's action "the equivalent of operating on the wrong limb or organ" and stated that "either Respondent [Arbit] had no idea what level he was supposed to operate on, or he operated on the wrong level. Either scenario is egregious."

The committee added that the "Respondent's conduct as to [10 other] patients shows a pattern of poor documentation and inattention to details of good clinical practice," noting that the "Respondent was disciplined by the New York State Board for Professional Medical Conduct four years ago. In that case, Respondent never adequately examined the patient's chart, MRIs, or even the patient before surgery. One would expect that the experience of four years ago would have sufficiently chastened Respondent to ensure utmost caution, documentation, and patient attention to prevent a reoccurrence of misconduct. Apparently, that was not the case for the November 1998 surgery on Patient H."

In 1995, Arbit operated on the wrong side of a patient's brain during surgery at Sloan Kettering Memorial Cancer Center. He subsequently received a censure and reprimand, one-year probation including practice monitoring, and a $10,000 fine after signing a Consent Order in which he agreed not to contest the department's charges.

In the current disciplinary action brought against Arbit, specifications of misconduct involving the 10 other patients were not sustained. Panel members were divided regarding misconduct specifications stemming from an operation in which Arbit again was accused of operating on the wrong side of a patient's brain produced a split ruling. Two members of the hearing committee voted not to sustain the charges. The dissenting panel member found the testimony of a physician assistant who was present during the operation to be compelling, and voted to sustain the allegation that Arbit surgically explored the patient's left cerebellum area, although the tumor was on the right side of the patient's brain.

Novello vows to appeal the committee's decision on the appropriate penalty, saying the only appropriate action is to revoke Arbit's license. ■

Healthcare Risk Management's
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Patient falls in recovery room, landing on just-operated knee: $175,000 verdict

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News: After arthroscopic knee surgery, a patient rose from her bed in the recovery room to walk and fell on the knee that had just been operated on. A jury returned a $175,000 verdict of negligence against the hospital.

Background: The patient, a 51-year-old woman, went to the hospital for minor arthroscopic surgery on her right knee. She had chondopathy, which is the loss of cartilage. Several hours after the procedure, she was recuperating in the recovery room. She asked a male hospital staff member to raise her right leg. The staffer did so, placing her right foot in his hand. The patient later recalled that the staff member announced, "She's ready." Moments later, she was assisted in rising to stand on both feet. She said she took one step, immediately fell forward, and landed on her right knee. She said she felt no pain from the fall. The patient was immediately helped up off the floor by staff who were present.

Several hours later, numbness from the anesthesia faded, and she reported intense pain in her right knee, the knee that had just been operated upon. One month later, she underwent a second corrective knee surgery on her right knee. Additional medical bills of $7,686 were incurred in the subsequent surgery.

The plaintiff brought suit against the hospital, claiming recovery room staff personnel failed to adequately or accurately establish her level of recovered neurological functioning, which led to staff allowing her to stand too soon. The plaintiff introduced expert testimony from an internal medicine specialist who emphasized that, given the patient's period of anesthesia, she had not been properly assessed prior to being instructed to stand. The expert concluded the failure to assess the patient's neurologic recovery prior to insisting that she was ready to stand and walk constituted negligence. The same expert linked the reinjury to the fall. The plaintiff testified that she cannot place full weight on the injured right knee and that the knee would often lock up. The hospital denied liability, saying that the patient said she was unable to walk or stand by herself so the staff gently eased her to the floor. The defense introduced expert witness testimony of a hospital liability analyst, who supported the hospital's interpretation of events. Further, according to the hospital, the event was so minor it was not charted in the plaintiff's hospital medical record chart. The hospital's expert concluded the assessment and monitoring by the hospital recovery room staff was adequate and proper, and that staff noticed no sign of injury.

When asked about the plaintiff's report of pain in the right knee several hours after the fall, the defense expert linked this pain to the surgery performed earlier that day.

The jury sided with the patient and awarded her $175,000 in damages.

What this means to you: When a patient falls in the hospital, particularly in a well-staffed recovery room, there is a presumption that the incident could have been avoided. And when patients fall on a spot where they have just had surgery, the presumption is strengthened, especially when the occurrence has not been documented one way or the other.

"Protocols should be in place for assessing all patients following surgery, whether the surgery is being performed as an outpatient or inpatient procedure," observes **Ellen L. Barton**, JD, CPCU, a Phoenix, MD-based risk management consultant. "These protocols should address which of the staff has responsibility for specific tasks and what the objective criteria are for those tasks based on the type of surgical procedure, type of anesthesia, length of time in recovery, as well as patient specific measures as individual cases may merit. In addition, protocols should specify how patients are to be assisted in standing for the first time, such as the minimum number of minutes a patient should sit in an upright position prior to standing with assistance. Unfortunately, it appears from the incident and lack of any documentation to the contrary, that if such protocols were in place, the staff did not follow them.

"Given the number of staff seemingly present at the time of the untoward event, it is likely that the patient may have not actually fallen, but buckled at the knees. Regardless of how or why the patient fell or touched the ground, the hospital still had the responsibility to properly document the event. If the patient had indeed been unable to stand or walk without assistance, the fact should have been recorded. The documentation might also have given the hospital a leg to stand on when arguing its version of the facts. Saying that the event was so minor that it did not merit documenting simply did not vindicate the hospital of its responsibility to track the care provided to its patient. Everything about a patient's condition should be documented. Even if the postoperative patient had jumped off the table and waltzed, the moment should have been recorded. In addition to documenting the event, staff would have been well-advised to mention the incident to the next-of-kin or the person responsible for driving the patient home. If the patient had been prone to buckling, then the next person to whom her care was entrusted should be made aware of the potential situation," adds Barton.

"In summary, staff education cannot be emphasized enough. Knowledge of and exposure to the protocols and procedures designed to maximize patient care should be one of the risk management program objectives, as should be touting the merits of appropriate, adequate documentation," states Barton.

Reference

• *Brown v. St. Margaret Mercy Healthcare,* Lake County (IN) Superior Court, Case No. 45D01-9712-CT-1261. ■

Elderly patient falls twice: $670,000 Texas verdict

News: While hospitalized for pneumonia, an elderly patient fell twice. One fall was attributed to a commode breaking underneath her, and the second occurred when her bedrails were left in the down position. Injuries from the successive falls resulted in the need for her to be placed in a long-term care facility after discharge from the hospital. Even though she had no recollection of the second fall, a jury awarded $670,000 to the patient.

Background: The plaintiff, an 87-year-old widow, was admitted to the hospital for treatment of pneumonia. Prior to admission, the plaintiff had lived independently in an apartment for 26 years, despite blindness in her left eye from a childhood injury. Upon admission, she was assessed as being a high risk for falls due to generalized weakness from her pneumonia, partial blindness, and a history of falls.

The plaintiff was being assisted in using a bedside commode when the leg of the commode broke, causing her to hit her head and fall to the floor.

In the course of hospitalization, the patient also began to suffer from intestinal bleeding, which lead to her need to be catheterized while sedated. Following one such procedure, upon returning to her room, an EKG technician arrived and asked the family to leave so that she could perform the EKG. After the EKG, the technician left the bed elevated in the highest position and left the two lower side rails down.

About an hour later, a nurse went to the room and found the plaintiff lying in a pool of blood on the floor. The plaintiff was cleaned up and put back in bed.

The plaintiff had no memory of the second fall, but she apparently fell out of bed while unattended. As a result of the fall, the ocular globe in her right eye was ruptured. Since her left eye had been injured in a childhood accident, this rendered her essentially blind. The patient alleged negligence in providing an unsafe commode for patient use and for leaving her unattended with the bed two of the four side-rails down. The plaintiff, independent before the accident, moved into a long-term care facility.

The defendant argued there was no credible evidence that the plaintiff fell out of bed. The defendant hospital argued the position of plaintiff's body on the floor suggested that she had gotten out of bed and then fallen. The defendant said the plaintiff's deteriorating health would have eventually necessitated long-term care. The defendant also argued the plaintiff failed to mitigate her damages through physical therapy and potentially corrective surgery.

The jury awarded the plaintiff $670,000 in damages.

What this means to you: There is a basic rule in patient care: Take the patient as you find them. This is certainly the case with elderly patients. With specific-need elderly patients, different rules often apply.

"Although this patient had been living independently, which would normally indicate a mobile, but albeit, elderly patient, she was assessed at admission as being high-risk for falls," says **Ellen L. Barton**, JD, CPCU, a Phoenix, MD-based risk management consultant. "If the system for assessing her as high risk was in place, it stands to reason that there were protocols in place for handling patients once they were labeled; otherwise, there would be no need for the label. Once deemed high risk, protocols should at a minimum address the use of equipment and communication among staff when the patient's care is transferred from one person to another.

"Decisions regarding equipment may be critical in the care of a high-risk patient. Someone probably should have assessed whether it was safer to use a bedside commode or have the patient assisted to the bathroom. Perhaps this was done, but regardless once someone made the decision to use the bedside commode, the hospital bore the responsibility for maintaining and servicing the piece of equipment as well as assuring that staff members charged with the use of the equipment knew how to operate it and should have recognized when something might be wrong with it. This generally involves staff training in the use and operation of equipment as well as an regular equipment safety check by the hospital engineering department," adds Barton.

"Further, when a high-risk patient is transferred from staff to staff, the present caregiver should notify the other of the patient's condition. In this instance, this would have included the charge nurse passing along the information to the EKG technician and sharing with the tech the need to raise the bed rails and keep the bed in the lowest of the positions. When a patient has been identified and labeled as high risk, it generally means that additional precautions must be taken and those aware of the potential should be a position to communicate that fact to others involved in the patient's care," concludes Barton.

Reference

• *May Henry v. San Angelo Community Medical Center,* Tom Green County, TX District Court, Case No. C-99-0457-C. ■

Fall leads to partial paralysis: $4.5 million

News: While on the way to see her supervisor, a hospital employee slipped and fell on a recently mopped floor. She alleged she herniated a disc in the fall and became partially paralyzed. She prevailed in a jury trial and was awarded $4.5 million in damages.

Background: The plaintiff worked as a nurse, treating and evaluating homebound hospice patients for a company that rented space from a hospital. She had ventured from the patient area to drop off paperwork, see her supervisor, and perform other work-related nursing duties. A large area of the floor recently had been mopped, including the hallway between the area known as the activity room and the ladies' restroom. Passing through that area, the plaintiff slipped in water on the hallway floor.

As a result of the slip and fall, the plaintiff maintained that she sustained thoracic disc herniation, which depressed her spinal cord, leading to partial paralysis. Because of the paralysis, the plaintiff has to cauterize herself at least four times a day, given

that she has no sensation in her vagina. Plaintiff also claimed that she suffers from chronic yeast infections as a result of the antibiotics she has to take, has trouble defecating, and developed complex regional pain syndrome, which causes burning in the chest area. She has to walk with a cane most of the time.

The plaintiff alleged the floor was covered in white linoleum with a high-gloss shine. Coupled with the fluorescent lighting in the area, she said it made it difficult for her to see the water. Furthermore, there were no warning signs posted. According to the plaintiff, those conditions caused her to slip and fall.

The defendant claimed the plaintiff's injuries were merely a continuation and worsening of injuries that she received in prior accidents. The jury awarded a verdict in the amount of $4.5 million. However, the plaintiff was found to be 40% negligent, which reduced her award to $2.7 million.

What this means to you: Slips and falls are not limited to patients. Hospitals, like other businesses, should offer their patients, employees, and visitors a safe workplace.

"The housekeeping staff in this instance, clearly had the responsibility to keep the floor clean; however, they must do so without causing harm. At a minimum, the placement of a 'wet floor' sign is generally considered necessary," says **Ellen L. Barton**, JD, CPCU, a Phoenix, MD-based risk management consultant.

"While the jury found some part of the fault on the employee, it also found that the hospital was negligent. This not only begs questions of any pre-existing conditions the nurse might have had, but also covers issues such as what type of footwear was she wearing, was she holding anything that would have prevented her from seeing the floor, and did she wear corrective lens and did she have them on?

"Given the fact that hospitals operate on a 24-hour/seven-day-a-week basis, one wonders if, in this instance, the housekeeping staff were following the standard operating procedure for cleaning the floors. Conversely, if the staff were in compliance with the time standards, it appears that prescribed precautionary steps might not have been taken. In addition, was the flooring adequately safe? The plaintiff's testimony, it appears the white floor plus no signs eliminated the possibility of a plaintiff having last clear chance to avoid the accident," states Barton.

Reference

• *Tamara L. Grosso v. Tenet Healthsystem Hospitals Inc., d/b/a Hollywood Medical Center, f/n/a NME Hospitals Inc.* Broward County (FL) Circuit Court, Case No. 97-08554 12. ■