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Just because a lawyer can read consent forms doesn't mean that a patient can

It's not enough to write for a lower reading level

Risk managers have been more worried lately about the informed consent forms their institutions use since it has become apparent the forms can backfire. An informed consent form that doesn't properly inform the patient can be used against you in court later, and writing a good one is more difficult than you can imagine.

Simply writing the informed consent form for a lower reading level may not be enough, experts say. The best solution may be to actually get patients involved in the process.

But that's the case only if you really want patients to understand the consent form, says **Mark Hochhauser**, PhD, a psychologist in Golden Valley, MN, who specializes in readability consulting and works extensively with health care providers. For years, he says, lawyers and risk managers have seen informed consent forms primarily as a way to protect the provider against lawsuits, not necessarily a way to tell patients what they need to know. The two goals don't have to be incompatible, he says, but over the years, health care providers have let the informed consent document drift decidedly into the former camp.

"Most of these forms are written by lawyers in legalese, then handed to sick people to decipher," he says. "The purpose is not really to get informed consent, it's just to keep people from suing you. You have to have language in there to protect the institution, but if that's all there is, you're not getting informed consent."

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Hochhauser says the problem is rampant throughout the health care industry and, in many cases, providers are trying unsuccessfully to do the right thing. He says he recently saw a health care facility that printed a lengthy "Patient Bill of Rights" to help patients, but it was written at a postgraduate reading level.

"For your typical hospital patient, that's incomprehensible," he says. "What's the point?"

The backfiring form

Hochhauser says a recent case involving Tampa (FL) General Hospital illustrates how a consent form can backfire when it is designed only to protect the hospital. The hospital and the University of South Florida (USF) recently agreed to pay a $3.8 million settlement to plaintiffs claiming they consented to medical research studies but did not understand the consent form. The hospital paid $1.1 million and the university paid $2.7 million.[1]

In effect, the defendants claimed the hospital performed procedures on them without their consent. USF researchers focused on women at high risk of delivering small, premature babies. The women were treated with corticosteroid injections and had to undergo amniocentesis, sometimes repeatedly. The lawsuit alleged that "defendants engaged in a policy or practice of conducting randomized medical research studies on the named plaintiffs and other similarly situated pregnant females without obtaining lawful informed consent from them." The case was litigated for 10 years and, in the consent decree filed in November 2000, the hospital and university still denied the charge but agreed to improve the consent process.

"USF shall implement a policy requiring that

Clarification

In the December issue of *Healthcare Risk Management,* an article stated that the Physician's Insurance Company (PIC) of Wisconsin is recommending the use of active electrode-monitoring technology to reduce risks in laparoscopic surgery, saying the machine could reduce malpractice claims. PIC says it is not officially recommending or endorsing the technology, but has alerted its members that it may be worth considering as an extra measure of safety. ■

USF researchers, when engaged in research studies involving pregnant women at Tampa General Hospital, will apply a standard readability test to research consent forms prior to their submission to the IRB [investigational review board]," the consent decree states. "The purpose of such policy is to provide help and guidance to researchers in the drafting and preparation of research consent forms. At its option, USF may terminate this policy, on a prospective basis only, seven years after the approval date."

The decree also requires that $25,000 of the funds paid by the university be used to help the school's researchers design improved informed consent documents. Hochhauser studied the consent forms at issue in the case, and says they required a reading level equal to two years of college. The forms provided the necessary information for the patient, he says, but only if the patient could understand them. He is certain that very few could.

"The USF case didn't get much attention, but it deserves it," Hochhauser says. "The consent form wasn't different from what is used at institutions across the country, but they eventually had to come to an agreement that those patients didn't know what they were agreeing to. It cost them a lot of money."

Review and improve

Stephen Moore, JD, partner in charge of the corporate health services section at the law firm of Hinshaw & Culbertson in Rockford, IL, says health care providers risk significant liability if they do not review and improve their consent forms. Though the forms may not provide a basis for a lawsuit by themselves, they may factor into other malpractice claims.

"If the form is not readable by an average person, you don't really have a useful form at all," he says. "A form that is difficult to understand actually could be produced in court and serve to prove the case that the patient was confused and did not understand the risks."

When reviewing a consent form, Moore suggests you consider how it would sound if read aloud to a jury during a malpractice trial. Imagine the form being read aloud by a smarmy plaintiff's attorney using a good measure of sarcasm. Consider how the jury would react. Would it think a reasonable, average person would understand the consent document? Or would it dismiss the form as gobbledygook that no one but a lawyer could understand?

"The document must be easy to understand or it has little value and actually can be harmful to you," he says. "I've heard of a number of cases in which the plaintiff alleged that the form was so indecipherable that they didn't understand what they were consenting to. That can be damaging."

Even so, a poorly written consent form is not likely to spark a lawsuit all by itself, Moore says. Rather, the consent form can create added exposure when the provider is sued for whatever went wrong in the procedure.

"Remember that if you don't have informed consent, you have technical battery once you put your hands on that person," Moore says. "We do see some cases where there was no harm to the patient at all, but patients have filed claims of battery because there was no informed consent. They usually don't get any substantial payout when that's the case, but the consent issue can be significant when it's tacked on to other claims."

Follow the money

While the issue has gained more attention in recent years, Hochhauser says providers still aren't doing much to improve consent forms. The USF case should provide a financial reason to provide better consent forms, he says.

"Things are improving, but improving very slowly," he says. "It will take more high-profile cases to get people's attention. It's just not a high-priority issue for most hospitals, and it won't be unless they see a real compelling reason to do something, preferably with a financial incentive."

Hochhauser says all health care providers should review their consent forms and make an effort to improve them. Writing them at a lower reading level will help, he says, but don't be lulled into thinking that is the whole problem. Rewriting the consent form for a lower reading level may address only some of the issues that prevent the patient from truly understanding the exchange. **(See p. 28 for more advice on how to improve consent forms. See p. 29 for suggestions on other improvements.)**

Changing consent forms may prove a difficult task for risk managers, Hochhauser says. Even if the risk manager can overcome the tendency to write in a stuffy, academic manner, there may be many other egos to deal with. It is not uncommon for doctors, lawyers, and administrators to resist any attempts to make the consent form easier to understand, he says. Some resistance comes from people who would rather write in a complex way

to show off their language skills, and some comes from simply not understanding the limits of the average person's reading and comprehension. Lawyers and doctors can be accustomed to communicating with people with high educational levels and forget that the average patient may be quite different.

On a more cynical level, Hochhauser cautions that some hospital leaders, especially legal counsel, don't want the patient to understand the form better.

"Some lawyers argue that if you change the wording, you make it more likely you'll be sued," he says. "They're saying that if people really understand what we're doing here, they'll sue us. So let's confuse them so they don't understand and don't know to sue us. I don't think that's how you want to run your hospital."

Reference

1. *Diaz, et al. v. Hillsborough General Hospital Authority, et al.*, Case No. 90-120-CIV-T-25B, United States District Court for the Middle District of Florida, Tampa Division. ■

Look for new ways to simplify forms

Any significant improvement in the usefulness of informed consent documents requires a new approach from the provider, says **Mark Hochhauser**, PhD, a psychologist in Golden Valley, MN, who specializes in readability consulting and works extensively with health care providers.

Writing the documents for a lower reading level is good, but that is only the beginning, he says. "If you write at a lower grade level, you usually cut long sentences into shorter sentences. [This leads to] very choppy reading. If you cut a 50-word sentence into three 17-word sentences, the grade level will come down, but it still might not be easier to read in any meaningful way."

Here is Hochhauser's advice for improving informed consent documents:

- **Start from scratch.**

You'll be more successful if you write a new document, including all the elements that you decide are necessary, rather than taking the old version and trying to improve it.

- **Watch for word familiarity.**

Word familiarity probably is as important as sentence length, Hochhauser says. People won't understand a document full of unfamiliar words, even if the sentence structure is short and simple. Look for opportunities to use more familiar words. Don't say, "Possible adverse reactions include contusions" when you can say, "You might get a bruise." **(For suggestions on word choices, see p. 29.)**

- **Define abstract concepts.**

Remember that doctors and lawyers are more used to some abstract concepts than the average patient. "Randomness" is a good example. If the consent form for a study states the patient's treatment will be determined randomly, you might add, "like by flipping a coin."

- **Use images, other tools to explain.**

Look for nontraditional ways to explain concepts to patients. If the wording of a document is trying to explain how a medical device works, maybe it should use a photo or diagram of the device. Explain quantities in real-world terms, such as teaspoon and quart. Use comparisons to familiar household objects when explaining size.

- **Write in the first person ("I consent . . .") or the second person ("You consent . . ."), but not both.**

Either format works, but avoid switching between the two. That's confusing to the patient.

- **Avoid using multiple subjects such as "You/Your spouse/Your minor child."**

Many forms use this technique to try to cover all possible situations. But it often just confuses the reader and depersonalizes the form. Instead, word the document carefully so that it applies to most situations, or use different documents for different people.

- **Involve patients from the beginning.**

The best method for ensuring the average patient will understand the document is to let them help you write it. Put together a focus group and explain to them what the procedure or study involves, and listen carefully to the questions they ask as you explain. Note where they stop the doctor and ask for clarification, or where their eyes begin to glaze over and it's clear you've lost them.

Once they understand the concept, ask them how you should explain it to others just like themselves.

- **Have patients critique the new form.**

Once you have written the new consent form, have a different focus group of patients review it. Give highlighters and leave them alone to read the document with instructions to highlight any

word or part they are do not fully understand. That should help you pinpoint what parts need more work. This method also can be useful in revising existing forms.

As an alternative, you can even take the forms home to your teen-age children and ask them to read them and explain the contents.

"You really have to focus on the reader and what it will take for them to understand it," Hochhauser says. "You'll find that they want to write things in much plainer language than you ever would have dreamed of. But that's what you have to do sometimes." ■

Simplify, no matter how much it hurts

Writers will tell you it is much harder to write clearly than it is to sound brilliant. When writing consent forms, the risk manager should use the most basic, widely known terms instead of those that sound needlessly impressive or academic.

The University of Illinois at Chicago's Office for Protection of Research Subjects has recommendations for writing consent forms clearly. Much of the advice can be found on-line at http://www.uic.edu/depts/ovcr/oprs/Forms/consent.html. Here are some of the school's recommendations for choosing words carefully:

Instead of:	**Try:**
• acute	recent, sudden
• adverse effect	bad side effect
• assay	lab test
• benign	not malignant, usually without serious consequences
• bolus	an amount given all at once
• carcinogenic	capable of causing cancer
• catheter	a tube for withdrawing or introducing fluids
• chronic	continuing for a long time
• clinical trial	an experiment with patients
• controlled trial	a study in which the experimental procedures are compared to a standard (accepted) treatment or procedure
• culture	test for infection, or organisms that could cause infection
• diagnostic instrument	questions
• double blind	study in which neither investigators nor subjects know which drug the subject is receiving
• dysplasia	abnormal cells
• edema	increased fluid
• efficacy	effectiveness
• extravasate	to leak outside of a blood vessel
• hematoma	a bruise, a black and blue mark
• heparin lock	needle placed in the arm with blood thinner to keep the blood from clotting
• monitor	check on, keep track of, watch carefully
• morbidity	undesired result or complication
• mortality	death or death rate
• necrosis	death of tissue
• oncology	the study of tumors or cancer
• percutaneous	through the skin
• placebo	a substance of no medical value, an inactive substance
• PRN	as needed
• protocol	plan of study
• random	by chance, like the flip of a coin
• relapse	return of a disease
• retrospective	looking back over past experience ■

Reading levels may be just the start

The reading level of your consent forms is important, but it is not the only reason you might want to review and improve the documents, says **Sandra K.C. Johnson**, RN, ARM, FASHRM, regional risk manager at Imperial Point Medical Center in Fort Lauderdale, FL.

Johnson and her colleagues recently revised their consent forms, partly to consolidate myriad documents in use at the time and partly to take a new, more streamlined approach to obtaining

consent. Her system's four hospitals and 38 ambulatory centers were using a wide variety of consent forms, but Johnson wanted to consolidate them about a year ago. Previously, the various centers required consent for actions that didn't need consent, and there was no uniformity.

Readability is a good reason to review consent forms, Johnson says, and she made sure the revised consent forms were written at a much lower reading level than the previous ones. But she also suggests risk managers check other potential problems and improvements at the same time.

Johnson and her colleagues decided to make the consent forms simpler than anything they used before. For invasive medical and surgical procedures, the document affirms the patient has received informed consent from the surgeon and has no more questions. That approach stems from case law indicating the informed consent for procedures is the responsibility of the physician, not the hospital.

"The physician can use whatever consent process and document he or she wants, but we don't want to hold ourselves to a higher standard than we should by suggesting that we are responsible for the informed consent process," she explains. "We even took a hard-line position and said we would not have the physician sign our informed consent document because we don't want to put ourselves between that physician-patient relationship."

The invasive procedure consent also explains a few other things, such as the possibility that blood or general anesthesia may be necessary after the procedure starts, the possible use of any tissue removed from the patient, and the option to prohibit any nonclinical visitors in the operating room.

For all other consent in the hospital system, Johnson developed a general consent for treatment. The old one was two lines that stated "you could do anything to the patient, including surgery and giving blood," she says. The newer version is less inclusive, amounting to permission to examine the patient and explaining billing procedures. ■

The good, the bad, and the final rule

The U.S. Department of Health and Human Services (HHS) has announced final regulations addressing self-referrals by physicians, intended to protect beneficiaries and taxpayers from potentially abusive referral patterns while making it easier for physicians and providers to comply with the law. The effect on providers could be small or large, depending on individual circumstances. An attorney familiar with the issue says risk managers must analyze the situation immediately.

The self-referral regulation, known as the Stark rule, prohibits physicians from referring Medicare patients for certain health care services to entities with which the physicians or their immediate family members have a financial relationship. A financial relationship can be either an ownership interest or a compensation arrangement, and can be direct or indirect. The law also contains a number of exceptions.

The HHS' Office of Inspector General says its studies and those of other governmental agencies show referrals to entities in which physicians have a financial relationship encourage excessive use of those services. In certain cases, the practices also are considered unethical by the American Medical Association. HHS Inspector General **June Gibbs Brown** says there was enough fraud to justify the regulation.

"We believe this statute is a powerful deterrent to fraud and abuse," she says. "The regulation will be another strong step in the department's efforts to reduce waste, fraud, and abuse in the Medicare program."

Major changes from proposed version

Morris Henry Miller, JD, chairman of the health law practice area for the law firm of Holland & Knight in Tallahassee, FL, says risk managers should make a careful assessment of how the final regulation on self-referrals may affect any physician groups within the organization. The news is not all bad, he says, but adds the real effect of the legislation can only be determined by analyzing specific situations.

The changes from the original proposal relax some previous requirements and tighten others, Miller says. Risk managers must study the regulation carefully to determine which portions apply to their physicians.

"On the whole, this probably makes things a little easier for physicians than they were in the

1998 proposed regulations," he says. "For example, within a group practice, it relaxes somewhat the level of supervision a physician group is required to provide to employees providing ancillary services. The 1998 regulation would have required physicians to be on site any time ancillary services are provided. The final regulation backs off that position and allows supervision under some usual parameters."

What's my motivation?

Some of the changes could mean trouble nonetheless. Miller says he suspects most physician groups will not have to make major changes to comply with the regulation, but that's no reason not to look carefully. If you *do* have to change your practice to comply with the new regulation, there is a major motivation to do so.

The physician referral law provides a variety of sanctions, including denial or refund of payment and civil monetary penalties. Consistent with the proposed rule, the final rule prohibits physicians from making referrals for the targeted services to most entities which the physicians own in whole or in part. In contrast, the final rule generally permits physicians to refer to entities in which they have a compensation relationship, as long as the compensation paid to the physician is no more than would be paid to someone who provided the same services but was not in a position to generate business for the entity.

"You could have some specific types of arrangements that have to be changed," Miller says, citing the example of lithotripsy ventures that have proven quite popular with some physician groups. "In 1998, they said they wouldn't consider lithotripsy a designated health service subject to Stark even when it was provided outpatient in the hospital. But the final version says lithotripsy is a designated health service like any other."

That means physicians invested in lithotripsy services must take at look at how those services are structured. If the physician partnership leases the lithotripsy equipment and then subleases it to a hospital, Miller says the new regulations will require the rent under that sublease be no more than the pro rata portion paid under the prime lease. In other words, no profit. But if the physicians own the equipment outright and lease it at a fair-market rate, the self-referral regulation may have no effect on that arrangement.

Miller also cautions risk managers to take a close look at part-time leasing arrangements for diagnostic imaging equipment. The new regulation cracks down on those arrangements when the diagnostic imaging equipment is not in the same facility as the physicians' group practice.

"The rules make it clear that the group practice can't make referrals to that facility if the only interest is a part-time lease," Miller says. "But if it's in-house, that can still be OK. Again, it depends on the specific circumstances, so you have to look carefully."

The final rule also clarifies some of the exceptions to the self-referral prohibition and offers clear guidance regarding how to structure financial arrangements to comply with the exceptions. To give physicians time to adjust existing business arrangements that would not previously have triggered the referral prohibition, the rule becomes effective Jan. 4, 2002.

Robert Berenson, acting deputy administrator of the Health Care Financing Administration (HCFA), the agency that runs Medicare, says most providers should have no trouble complying with the new regulation. He says the final rule also substantially reduces the potential financial liability of hospitals and other entities that provide any of the targeted services and submit claims for prohibited referrals, if they neither knew nor had reason to suspect that they had an indirect financial relationship with a referring physician. Under the proposed rule, any claim submitted by an entity for services rendered pursuant to a prohibited referral would have been denied, even if the entity had no reason to suspect it had an indirect financial relationship with the referring physician.

Rule designed to avoid financial motivation

In defining what practices the law exempts from the self-referral prohibition, the final rule expands the law's exceptions for services provided in a physician's office and services provided by managed-care plans. In addition, it allows exceptions to permit certain indirect compensation arrangements, allow small, nonmonetary gifts, and protect financial arrangements between academic medical centers and their faculties if certain criteria are met.

The self-referral law, as enacted in 1989, prohibited a physician from referring a patient to a clinical laboratory with which he or she (or an immediate family member) has a financial relationship. Effective Jan. 1, 1995, Congress

extended the law to prohibit a physician from referring patients to providers of 10 other categories of health care services if the physician (or an immediate family member) has a financial relationship with the service provider. The 10 affected services are: physical therapy services; occupational therapy services; radiology services and supplies; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. The law also prohibits an entity from billing for services provided as the result of a prohibited referral.

The provisions in the physician self-referral rule complement other laws designed to combat waste, fraud, and abuse, including the anti-kickback law. Potentially abusive financial relationships that may be permitted under the physician self-referral law could be addressed through other laws.

HCFA published a final rule covering physician self-referrals for clinical laboratory services on Aug. 14, 1995. The agency then published a proposed rule to implement the expanded law in 1998 and received almost 13,000 comments from the public. The new final rule modifies the proposed rule, addressing the most contentious issues raised in the proposal.

HCFA intends to address in another final rule comments received on provisions of the proposed rule that are not addressed in the final rule. The second final rule also will address public comments on the final rule. HCFA says it intends to move as quickly as possible on the second rule.

Watch for violations of kickback rules

Miller offers one last word of advice for risk managers assessing their group practice operations: Don't be lulled into thinking everything is fine once you comply with the new self-referral regulation. There are other traps out there that don't change with this new rule.

The penalties can be severe if you overlook an arrangement the government deems improper. As a minimum punishment, the group practice will have to return any Medicare funds received as a result of the improper arrangement, but Miller says the result could be worse. The investigation into the self-referral violation could be an open door to other investigations that could find more problems. Even the portions of the practice that stand up to the self-referral scrutiny may not fare well under other standards.

"A Stark violation could be symptomatic of problems that show violations of the anti-kickback law or some sort of false claim. That could lead to more severe criminal or civil penalties," Miller says. "Just because you're complying with Stark doesn't mean you're OK with the kickback statute and other regulations. That could come as a surprise to some risk managers." ■

A new approach to judge staff training

The Joint Commission on Accreditation of Healthcare Organizations plans to develop a new approach to assess the effectiveness of staffing in health care organizations nationwide. The new process will use performance indicators to screen for potential staffing issues and will be pilot tested in 2001.

The effort is part of the Joint Commission's continuing commitment to identify and address potential opportunities to improve patient care quality and patient safety throughout its accreditation process. Effective staffing has been identified as a current issue of significant concern among health care professionals and the public.

The new assessment initiative, approved by a task force on accreditation process improvement, will draw upon both human resources and clinical outcome measures. Human resources measures will encompass all staff who provide health care services — including direct patient caregivers, such as registered nurses and respiratory therapists, as well as clinical support professionals responsible for pharmacy, laboratory, and radiology services. The approach is designed to emphasize the relationship between human resources and clinical outcomes, and recognizes that no single measure can reliably describe staffing effectiveness.

Two groups of measures — those identified by the Joint Commission and those self-selected and defined by each health care organization based on its unique characteristics — will be used. The fully developed approach will reflect the consensus of a broad-based expert panel convened by the Joint Commission in September 2000. Approximately 100 panel participants shared ideas on the best ways to improve the commission's current

approach to the assessment of staffing effectiveness and provided recommendations regarding those indicators which collectively would best serve as a screening mechanism for identifying staffing issues.

Current Joint Commission standards require accredited health care organizations to determine and provide the right number of qualified and competent staff to meet the needs of patients. Those determinations usually are based on internal formulae that reflect the numbers of patients and how sick they are. ■

Privacy rules: They're studied and challenged

The Chicago-based American Hospital Association (AHA) has asked the federal government to reopen some portions of the patient privacy rules adopted in the last days of the Clinton administration, hoping to delay implementation of the rules.

AHA executive vice president **Rick Pollack**, MD, wrote in a letter to Health and Human Services (HHS) Secretary Tommy Thompson that the rules pose "overwhelming" cost and implementation challenges for the nation's hospitals and health systems.

Real rules, real world

A study commissioned by the association says the cost to hospitals could reach $22.5 billion over five years just to comply with three key provisions of the rule. The rules also include "potentially confusing and burdensome consent requirements," Pollack's letter says. The AHA cites potential real-world problems, such as a doctor potentially violating the rule by discussing private issues with a patient in a hospital room shared with another patient. AHA also is concerned that the government's implementation schedule is overly aggressive.

"Hospitals are expected to be in full compliance with the new privacy rules by Feb. 26, 2003 — just a little over two years from now," Pollack wrote.

A review of the rule would allow hospitals to fully assess the impact of the rules and work with the new administration on reforming them, Pollack says. Delaying implementation of the rule also would allow hospitals to find additional sources of funding.

Issued in response to a congressional request for improving patient privacy standards as part of the Health Insurance Portability and Accountability Act of 1996, the privacy rules establish national standards for how personal health information is used and distributed, and set criminal and civil penalties for breaching patient privacy.

E is for ethics

On the same subject, the Chicago-based American Medical Association (AMA) and other groups recently released a report recommending more than 30 specific measures for protecting patient privacy. The AMA's Ethical Force, or E-Force, released the report. The E-Force Oversight Body's members include representatives from organized medicine, health care delivery organizations, patient advocacy groups, business, and government.

The E-Force selected two areas for ethics performance assessment based on their relevance to all participants in the current health care system. They include privacy and confidentiality protections in health care and processes for designing health benefits and adjudicating coverage decisions. The document is organized into eight content areas, each of which contains a set of corresponding performance expectations. This report will be used to create additional performance measures that organizations and practices can use for self-assessment, quality assurance, and quality improvement.

Mary Jane England, MD, an E-Force member, says the group is working to develop performance standards. One goal is to make the privacy policies of institutions and organizations clearly understandable to the public, allow individuals access to view and amend their medical records, and establish local review committees to investigate denial of an individual's request for information.

"Electronic information systems can provide tremendous opportunities to advance public health and improve patient care," England says. "But if patients withhold information, provide inaccurate information, or avoid the health care system because they fear the information they disclose might be used against them, then the most sophisticated electronic systems in the world will not be able to improve their health or the health of our communities." ■

Doctor supervision not needed for anesthetists

The Health Care Financing Administration (HCFA) has removed the longstanding rule that a physician must supervise nurse anesthetists, leading one side on the issue to praise their newfound freedom and the other side to warn of dire consequences.

The American Association of Nurse Anesthetists (AANA) hailed the new Medicare rule as "smart health care policy," saying it ensures access to safe, high-quality anesthesia care in medically underserved areas, especially in rural and inner-city hospitals where certified registered nurse anesthetists (CRNAs) often are the sole anesthesia providers.

The rule removes the federal requirement that nurse anesthetists be supervised by physicians when caring for Medicare patients, and defers to the states on the issue. Currently, the nurse practice acts, board of nursing rules and regulations, medical practice acts, and board of medicine rules and regulations in 29 states do not require physician supervision of nurse anesthetists.

"The practice of anesthesiology is not just administering anesthetic agents. It requires continuous medical judgment before the surgery . . . and even after surgery when recovery of the patient and [his] pain treatment are critical."

Rules of the game

The immediate effect of the rule, which became official when it was released in January, is that hospitals and ambulatory surgery centers (ASCs) will be able to receive reimbursement from Medicare without requiring surgeons or other physicians to supervise nurse anesthetists. This is consistent with the current Medicare rule, implemented in 1989, that enables nurse anesthetists themselves to be directly reimbursed by Medicare without a physician supervision requirement.

In addition, removal of the federal supervision requirement means seniors will now be cared for under the same rules and regulations that apply to all other anesthesia patients in their particular state. As stated in the *Federal Register*, "Under this final rule, state laws will determine which professionals are permitted to administer anesthetics and the level of supervision required, recognizing a state's traditional domain in establishing professional licensure and scope-of-practice laws."

Larry Hornsby, CRNA, president of the AANA, says the change means all surgical patients can now be confident they will receive the highest caliber of anesthesia care, even if they live far beyond the city limits. "This issue has never been about quality of care, but about access to care," he says. "AANA applauds HCFA for staying the course and ultimately carrying through with its initial plan."

The rule provides hospitals, critical access hospitals, and ASCs greater flexibility when it comes to staffing their anesthesia services, an important consideration for rural and inner-city facilities. Both the American Hospital Association and the National Rural Health Association supported the rule since it was proposed in December 1997.

Hornsby noted that 20 years ago, there were approximately two deaths for every 10,000 anesthetics given. Thanks to advancements in pharmaceuticals, monitoring technology, and anesthesia provider education, the current figure is approximately one death for every 240,000 anesthetics, he says.

11th-hour decision?

The American Society of Anesthesiologists (ASA) sees the issue differently. The ASA is calling on President Bush to reverse what it calls a "grievous and dangerous 11th-hour decision by the Clinton administration that places every Medicare and Medicaid patient having surgery at increased risk of injury or death."

The medical organization, representing 36,000 physician members nationwide, charged that the rule change will jeopardize the lives of seniors who undergo surgery by eliminating the requirement for a doctor to supervise if a nurse gives the anesthesia. **Neil Swissman**, MD, president of the ASA, notes that this requirement has been in effect continuously for the 35 years since the Medicare program was created.

"This action taken by the Clinton administration, with only two days remaining before leaving office, is an affront to everyone in this country — but in particular to our most vulnerable patients, senior citizens — who look to our federal government to

establish minimum standards for keeping patients safe," Swissman says. "Instead, the safety net that has protected millions of seniors over the years has been dropped right before the administration leaves town. It is simply incomprehensible that the administration could be so callous."

Major organizations support old rule

Swissman says independent researchers, every major surgical association, all 50 state medical societies, and the American Medical Association have supported retaining the rule. During the past year alone, the public decried the proposed rule change by sending more than 75,000 faxes and e-mails to Congress and the White House, and newspapers across the country published editorials supporting patient safety over politics. In Congress, more than 140 senators and representatives supported bills calling for research that would assure safety.

"There is a basic but critical misconception that has clouded this issue from the beginning," Swissman says. "The practice of anesthesiology is not just administering anesthetic agents. It requires continuous medical judgment before the surgery to diagnose the patient and determine the best anesthetics to use during surgery when split-second decisions are made, and even after surgery when recovery of the patient and [his] pain treatment are critical. Nurses are not doctors and should not be expected to make those decisions."

No scientific research to support change

Swissman contends there is no scientific research to support the rule change, and says there are studies that call such action into

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question as it regards the safety of patients having anesthesia. Last summer, University of Pennsylvania researchers published a paper that reviewed the care of 235,000 Medicare patients and determined there were 25 needless deaths per 10,000 cases when an anesthesiologist was not involved in the care.

"Instead of heeding the warning flags, HCFA chose to disregard the research rather than taking it to the next logical step," Swissman says. "To make it worse, HCFA still has offered absolutely no scientific evidence of its own that this change will maintain the current level of safety."

Feds wanted to decrease regulatory burden

According to HCFA's press release on the new rule, the decision was based on its "commitment to decrease regulatory burden by deferring to state licensing laws regulating professional health care practice."

All decisions relating to the supervision of nurse anesthetists will now take place at the state level. Some states require medical direction by an anesthesiologist while others maintain few or no standards at all. That is not the proper way for a federal program such as Medicare to operate, Swissman says.

"There should be one minimum federal standard of care so that seniors are not placed in medical jeopardy based on a patchwork of different regulations that currently exist throughout the country," he says. "For 35 years, no senior, whether in a small town or a big city, ever had to worry if a doctor would be involved in their anesthesia based solely on the state in which they were hospitalized. Now they will."

HCFA: Anesthesia care for elderly too risky

As recently as 1992, HCFA looked at this proposed rule change and said the anesthesia care of Medicare patients was too risky to leave to unsupervised nurse providers. "Nothing has changed in the training of nurse anesthetists that somehow qualifies them now to assume the medical responsibility of patients," Swissman says. "How can HCFA take a diametrically opposed position today when the only new scientific evidence suggests that doctors should supervise anesthesia nurses?"

The government also takes the position that anesthesia has become so safe that less qualified personnel can administer it.

"This misses the point completely," Swissman says. "Anesthesia is safer today than ever before *because* of the involvement of physicians. The safety figures that HCFA has quoted were based on studies in which an anesthesiologist was involved in every single case."

Nurses have two years of training

Anesthesia nurses have two years of technical training vs. 12 years of medical training for physicians. Swissman contends that level of training cannot prepare them for medical emergencies that inevitably arise during surgery. He says the ASA is reviewing all available options to overturn the rule change, which he characterizes as "a parting, potentially lethal gift" from the Clinton administration. ■

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Delay in hyperbaric chamber treatment leads to a $31 million verdict

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News: After surfacing with decompression illness, instead of being taken to a hyperbaric chamber three minutes from where his boat was docked, a diver was transported to a hyperbaric chamber 90 miles from the scene, delaying treatment for several hours. The delay in treatment allegedly resulted in severe injuries to the patient, including paralysis. A jury returned a gross verdict of $31 million, which was subsequently lowered to $22 million by the judge. The case has been appealed.

Background: On his birthday, the plaintiff, a recreational diver, decided to go fishing and scuba diving with a few friends despite the fact the weather was less than ideal on that October day. They had no food or water on board, but they all had been drinking beer. At about 3:30 p.m., the rains cleared and the group was about 15 miles offshore when they decided to do a 90-foot dive to a submerged barge. The plaintiff had been diving about 30 minutes and was on his ascent when he began feeling extremely weak. After surfacing, he called to those in the boat to come get him. The diver was in so much pain his friends had to pull him into the boat. His vision was blurry and his legs both tingled and were numb. He and his friends believed he was suffering from decompression sickness,and called the Coast Guard. They were instructed to take the injured diver to the Coast Guard dock.

In the meantime, the Coast Guard notified Divers Alert Network (DAN), a worldwide authority on diving injuries, and described the diver's condition. DAN personnel recommended giving the diver 100% oxygen and intravenously administering normal saline to address dehydration. The Coast Guard also called the local Emergency Medical Services (EMS), which notified the local hospital about the incoming patient. The emergency room physician then contacted the hospital at the local Navy base to see if it could care for the patient in its freestanding hyperbaric chamber. Though civilian patients generally are not accepted for treatment at military facilities, a Navy physician agreed to take the patient and began assembling the chamber's medical team. However, a senior physician at the community hospital determined that it would be better to have the hospital's helicopter pick up the patient and transport him to a coastal hospital 90 miles away that had a more sophisticated hyperbaric chamber.

The critical care beds at the Naval facility had been closed earlier that day, and the senior physician thought the appropriate bed might be available at the other hospital.

The ground EMS vehicle met the boat at the dock. The EMS crew started the saline IV and gave him oxygen. Unsure where to take him, EMS contacted the emergency room physician at the community hospital, who said that the helicopter

would be picking up the diver and transporting him to the hospital with the hyperbaric chamber.

Unfortunately, that was when things started going wrong. No one had notified the helicopter crew of the incident and the air ambulance did not have sufficient fuel for the 90-mile trip to the hospital with the hyperbaric chamber. The helicopter did initially transport him to the community hospital emergency department, where allegedly the next in the series of mishaps occurred. The patient's IV was changed from normal saline as was recommended by DAN to D5W.

Normal saline had been recommend for its ability to hydrate patients, which in turn generally helps prevent nitrogen in the tissue from coming out of solution and causing permanent damage to the spinal cord. The D5W solution is known to cause the spinal cord to swell, making it more likely to contribute to permanent damage. In addition, by changing the flow from constant flow to keep the vein open instead of helping to hydrate the patient, the line was merely kept open.

At around 6 p.m., the Navy hospital called and asked for the patient's location. The Navy's chamber was ready and the appropriate medical team had been assembled. The community hospital emergency physician informed the Navy that the patient had been stabilized and would be transported to the other hospital with the hyperbaric chamber.

Thirty minutes later, the helicopter transported the diver to the other hospital. En route, the helicopter maintained an altitude of 1,000 feet. During the flight, the patient experienced so much pain that he was given painkillers. When the diving accident victim arrived at the hospital with the hyperbaric chamber, he was paralyzed from his right shoulder to his feet and was blind.

There was no physician on hand to begin recompression therapy, as it seemed that the receiving hospital had not been contacted to prepare the chamber or assemble the requisite medical team. Given the potential for additional delay in care, the chamber technician violated hospital policy and began to treat the diver. While the plaintiff's sight and upper-body paralysis were restored, the diver's legs remained paralyzed. He had little or no control over his bowels or bladder and was in constant pain.

The plaintiff claimed that the series of mishaps significantly delayed his obtaining care necessary to address his condition, a severe case of the bends. He held that the community hospital personnel were responsible for delaying his initial transportation, administering the wrong IV fluid, aggravating his condition with unnecessary medical helicopter transports, and ultimately delaying his access to appropriate care and hyperbaric chamber treatment.

The plaintiff also claimed that the coastal hospital, located in a community where diving is promoted, was negligent for not having a specific protocol for handling injured divers with the bends.

The hospital responded that the diver knowingly engaged in a dangerous sport and did so carelessly. The hospital maintained that the plaintiff had been reckless by diving too long and too deep, which was the irreversible cause of his injury. It also averred that the diver had not been drinking water during the day but had been drinking beer before the dive so he was not well-hydrated, which contributed to his having a more extreme case of the bends.

It is rare that divers experience such symptoms before reaching the surface, which indicates he probably suffered from Type III decompression illness, which is more resistant to treatment — the person simply remains paralyzed and there is nothing that can be done for them.

The hospital said DAN recommends that patients should be examined in an emergency room for assessment and treatment of concurrent injuries, such as near drowning and head trauma, before being taken to a chamber.

The jury sided with the diver, awarding him $31 million, which was subsequently reduced to $22 million by the judge.

What this means to you: Hospitals located on the coast or near areas known for commercial or recreational scuba diving, particularly those operating hyperbaric chambers that treat diving accident victims, should at a minimum maintain protocols and procedures on the care and treatment of diving accident victims. Even those engaging in a potentially dangerous sport have an expectation for appropriate medical care in the event of an accident.

It is generally recommended that, when available, diving accident victims be treated in hyperbaric chambers located within hospitals, as opposed to freestanding units. While the Navy's chamber was not located within the naval base hospital's walls, it is not considered freestanding.

Even in the treatment of lesser-injured persons, divers undergoing decompression treatment for

the bends can experience adverse affects, which require the full backup of additional medical personnel and equipment as well as a critical care bed.

And it stands to reason that the more complicated the case, the greater the potential need for other medical care — and the greater chance for side emergencies such as oxygen seizures. Particularly, if a more extreme case of Type III decompression illness is suspected, the treatment may be of such duration and complication that a multimember chamber team and the most sophisticated equipment is desired, observes **Rick Herrick**, hyperbaric chamber director at Jackson Memorial Hospital in Miami.

This diver had extreme symptoms. Based on the information regarding the dive, it seems more likely that he had been diving longer and deeper than indicated. The diver may also have been more dehydrated than suspected, perhaps through heavy drinking or seasickness. The water temperature and his diving equipment may also have factored into the severity of his condition. The dive was on the borderline of safety based on standard dive tables in effect at the time of the incident. Since then, the tables have been modified and the dive would be considered more risky than before. While the severity of his symptoms would lead to more critical diagnosis, accuracy of the circumstances of the underlying incident are helpful to determine the best course of treatment, Herrick says.

Unless it's impossible to avoid, it is not recommended that bends victims be airlifted at more than 1,000 feet because the decrease in pressure can aggravate the condition.

As for the air transport of victims of diving accidents, hospitals and other entities operating air ambulances, even if the facility does not have a hyperbaric chamber, should have policies in place for dealing with persons with the bends. This is particularly true for air ambulance services located near diving spots. Protocols should address flying altitudes, information on the closest chambers, best treatment practices, and how to contact DAN. While raised by the plaintiff as an issue of negligence, it is generally considered acceptable patient care to fly at the standard helicopter altitude of 1,000 feet, notes Herrick.

For hospitals housing hyperbaric chambers with services available to diving accident victims, service should be available around the clock. Depending upon the use and demand for the service, 24-hour coverage can be maintained by an on-call team. Diving-accident victims are generally received through the emergency room and the acceptance of the patient is determined by the facility, not those operating the chamber. Given the potential need to provide the gamut of medical services, the chamber's manager or medical director should be consulted to assist in the assessment of diving emergencies at the facility. If the chamber is closed to diving victims, then all appropriate personnel in the hospital should be notified. This may include the transfer center, attending emergency room physicians, local EMS providers, and the administrator on duty, Herrick says.

Scuba diving is potentially dangerous, but when health providers and facilities are located in or near diving spots, medical personnel should be educated and trained on how to manage the care of injured divers. At the minimum, this may merely entail recognition of the potential for the bends and knowing who to call for assistance. As with many medical conditions, time is of the essence, and so there should be as few delays as possible in getting the accident victim to the right place by the right means, concludes Herrick.

Reference

• *Malcolm Keith Rawson vs. Baptist Hospital Inc.* No. 90-6078 CA 01, Escambia County (FL) Circuit Court. ■

Altering records: $75,000 in CA

News: A woman's dentist, who had treated her nearly five years, found significant decay on one of her molars and recommended a root canal. She returned to her former dentist for a second opinion. He found that several teeth had decayed and needed to be removed. The new dentist allegedly altered medical records, and destroyed and modified evidence to bolster his counter claim that the decay had rapidly developed and had not been years in the making, thus not overlooked by him. The case was settled for $75,000.

Background: After being a regular patient of her family dentist, the 59-year-old woman moved to a different city and changed dentists. She became a regular patient and had routine checkups at least three times per year. He had treated her for four-and-a-half years when he discovered significant decay on an upper molar and recommended she

have a root canal. Dissatisfied with the diagnosis and recommended treatment, she returned to her original dentist, who discovered severe decay of five teeth. He advised that all five teeth be extracted and replaced with a combination of a bridge and implants. The cost: approximately $15,000.

The patient contended that the defendant dentist failed to diagnose and treat the plaintiff's root decay and failed to provide adequate cleanings and periodontal maintenance. She claimed the failure to properly care for her teeth during routine checkups allowed her gums to recede, exposing tooth roots that are less calcified than the enamel-covered coronal portion of the teeth and are more susceptible to decay. The plaintiff also maintained the second dentist destroyed some of her dental X-rays and postdated other X-rays so that it appeared that the decay's onset and progression was extremely accelerated. The plaintiff's expert cariologist (tooth-decay specialist) said the earliest X-rays, which were claimed to be missing, had been relabeled in pencil.

The plaintiff also contended the dentist altered her records by adding the words "periodontal screening" to the records of several of her visits. The hard copy of her medical record, obtained prior to litigation being filed, had no entries noting periodontal screening. During his deposition, the defendant testified that the entries were made on the dates of the office visits.

Contrary to his deposition, in which he stated he performed the plaintiff's cleanings, she claimed the registered dental assistant performed her cleanings. If they included periodontal screenings, it was outside the scope of the dental assistant's duties as only dentists and hygienists may, by law, scale teeth under the gum line.

The defendant maintained that the onset of the decay began between two visits: the visit in which he found the decay and the one immediately preceding it. This claim was consistent with the X-rays he produced as evidence. Two days after the defendant was served with the plaintiff's Request for Admission and discovery sanctions relating to the medical records, the case was settled. At the settlement conference, the defendant indicated he would admit liability at trial to preclude the introduction of the alleged record alteration. The plaintiff received $75,000 in the settlement.

What this means to you: Altering a medical record, particularly to avoid a claim of medical negligence is generally grounds for disciplinary action by the professional's licensing board and also generally is considered fraud.

This is not to say that there are not circumstances that merit late entries and addendums to the medical record. But after-the-fact overhaul of the record is not customary practice, states **Jane M. Koubek**, special projects director at St. Anthony's Health Care in St. Petersburg, FL.

In institutional settings, policies and procedures should safeguard against such blatant alterations. The same should be true for all health care providers. At a minimum, late entries to a medical record should be signed and dated by the person making the entry. Late entries should be the exception, not the rule, and should only be made in emergencies, not in routine care matters, Koubek adds.

Medical records are the property of the health care provider, but the information contained in the medical record is the property of the patient. Even so, the release of such information should be done systematically and in accordance with patient confidentially laws and regulations in mind.

In some jurisdictions, law prescribes the requisite steps. At a minimum, Koubek suggests, health providers should use a standard release form containing these elements:

- Signature and date block for the patient (or the patient's guardian) requesting the record.
- Name and address of the health care provider / owner of the medical record.
- Full description of the information being requested, such as the time period requested and the specific information. For instance, a patient may only want the results of a blood test taken on a specific date as opposed to the entire record.
- Person(s) to whom the information is being disclosed.
- Purpose of the release.
- Period of time which the record information is valid. This is generally 60 to 90 days.
- The signature and witness of the person releasing the record.

As part of the medical-records process, all late entries and releases should be catalogued. Tracking information is critical, so what has been shared with others cannot be altered after the fact.

Reference

- *Sharon Brundage vs. Wayne A. Mathe, DDS, d/b/a Hillside Dental Group.* No. CV 46817, Tuolumne County, CA Superior Court. ■