

# the Reporter

## THE NEW HIPAA REGULATIONS TO DISCLOSE OR NOT TO DISCLOSE

by Robin Bowles, Risk Management Representative

*Editor's note: This article is the first in a series on new HIPAA regulations. Even as this article goes to press, revisions to the regulations are being considered. Most believe the revisions will be minor rather than the hoped for complete overhaul. Expect to see future articles as HIPAA compliance guidelines and revised forms become available.*

Begat by the cry for health care reform, the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), also known as HIPAA, was formulated. In a statement released on April 12, 2001, Tommy G. Thompson, HHS secretary, stated "President Bush wants strong patient privacy protections put in place now. Therefore, we will immediately begin the process of implementing the patient privacy rule that will give patients greater access to their own medical records and more control over how their personal information is used." The HHS office will begin issuing guidelines for implementation. The guidelines are intended to clear up some of the confusion regarding the impact of this rule on health care delivery and access.

Concerns to be addressed by the guidelines include:

- the ability to have access to necessary medical information on a patient you are treating
- patient authorization prior to obtaining consultations
- timely and efficient delivery of health care not hampered by confusion regarding consent forms
- parental access to information about their children including mental health, substance abuse or abortion

Goals for this rule include:

- improving patient care
- improving efficiency, security and protection of confidential health information
- standardizing of claim forms to a few universal

formats that will reportedly provide savings as well as increase efficiency, thus eliminating the administrative nightmare caused by the plethora of formats available for health care claims

HIPAA applies to all forms of records, not just electronic records. This was a change from the proposed rule. Health care providers will be required to develop a plan to secure health information. Health care providers must disclose policies and procedures for use and release of health information to patients. Disclosure for routine purposes such as treatment and payment of claims, will require a written authorization from the patient. Providers have full discretion regarding what information is sent to another provider for treatment purposes.

Non-routine disclosures (i.e., employer personnel decisions, financial institutions determining mortgages and other loans or selling mailing lists) will require a separate, specific authorization. State laws which provide a higher standard of protection (i.e., mental health, substance abuse, HIV/AIDS information) supersede HIPAA regulations. Of note, the recently approved Texas Senate Bill 11 bans the release of individual patient information for marketing purposes without patient consent.

Patient entitlements include the opportunity to request restrictions on the use and disclosure of health information and a disclosure history detailing all entities that received health information unrelated to treatment or payment within 60 days of the request. The right to review and copy their own records and to request corrections are also included in the provisions of this Act.

*continued on page 2*



*It has come to our attention that physicians are receiving materials via fax or mail marketing HIPAA compliance programs. Both TMA and TMLT will continue to provide the latest information on HIPAA through publications and in upcoming seminars.*

*continued from page 1*

#### **Risk management considerations**

- Assess your organization by revising existing policies and procedures, integrating the new HIPAA requirements. Develop additional written policies and procedures as necessary regarding access and release of health information for your practice including how it will be used and under what circumstances the information would or would not be disclosed to others. Providers may not refuse treatment because the patient refuses consent for disclosure. These written policies must be provided to your patients. Make sure they are reasonable, and that you can ensure compliance. Policies and procedures which are documented but not consistently followed create additional liabilities for your practice.

These policies and procedures must include the following to meet the requirements:

1. Routine disclosure policy and consent form
2. Non-routine disclosure policy and consent form which ensures informed and voluntary consent
3. Policy on handling of inquiries or patient complaints about privacy issues and a log for documenting these incidents
4. Policies should state that, except when transferred for the purpose of further treatment, the minimum amount of information necessary should be disclosed. Release authorizations should be specific.
  - Establish documentation requirements for release of records which could include a file check-out log and medical information release log.
  - Conduct and document a risk assessment which examines your business practices and physical facility for "privacy consciousness."
    - Conduct and document training for employees to ensure the internal protection of medical records. All employees should sign a confidentiality agreement which is maintained in their personnel file.
    - Designate a privacy officer to ensure that procedures are followed.
    - Provide physical safeguards for the medical records, computer systems, building and equipment from fire and other environmental hazards, as well as intrusion. Recommendations include daily back-up of patient information, storage of back-up diskette in a fire-proof safe and locking cabinets or rooms for record storage.
    - Implement protection, control, monitoring and access prevention processes to safeguard data transmitted over a communication network.

- Examine, if applicable, the following contracts for language that ensures the compliance of "business associates" with this rule:

1. software vendors
2. temporary personnel agencies
3. transcription services
4. answering services, especially text paging services
5. copying services
6. record storage facilities
7. trash removal

#### **Exceptions allowing disclosures without consent/approval**

- health care oversight, e.g., quality improvement, risk management
- public health, national security or defense
- research, with IRB or Privacy Board approved waiver of authorization
- judicial, law enforcement and administrative proceedings, determination of ID (deceased)
- emergencies
- facility patient directories

**If there is no other law requiring that information be disclosed, exercise your own judgment according to your policies and ethical principles.**

The date for physician practice compliance is April 14, 2003. The law provides for significant financial penalties for violations:

General Penalty for Failure to Comply:

- each violation: \$100
- maximum penalty for all violations of an identical requirement may not exceed \$25,000

Wrongful Disclosure of Individually Identifiable Health Information:

- wrongful disclosure offense: \$50,000, imprisonment of not more than one year, or both
- offense under false pretenses: \$100,000, imprisonment of not more than 5 years, or both.
- offense with intent to sell information: \$250,000, imprisonment of not more than 10 years, or both.

The regulations can be downloaded from DHHS's web site at [www.aspe.os.dhhs.gov/admnsimp/](http://www.aspe.os.dhhs.gov/admnsimp/).

#### **Sources**

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TEXAS MEDICAL LIABILITY TRUST

## SPECIAL PHARMACEUTICAL ANNOUNCEMENTS

August 2001

### Celebrex

On February 1, 2001, the Food and Drug Administration (FDA) issued a letter to the manufacturers of Celebrex (celecoxib), addressing repeated violative promotion of Celebrex. Pharmacia Corporation has engaged in promotional activities that minimize the potentially serious risk of using Celebrex and Coumadin (warfarin) concomitantly. The minimization of the risk raises significant public health and safety concerns because it minimizes the risk of significant bleeding. On two previous occasions, the FDA issued letters to Pharmacia objecting to the promotional materials for Celebrex that, among other violations, minimized the Celebrex/Coumadin drug interaction. Pharmacia assured the FDA that corrective steps had been taken in order to prevent future violations of this type; however, the activities have continued.

The violations include promotional audio conferences presented on behalf of Pharmacia by Dr. James McMillen. Programs present false and/or misleading information, including:

- minimizing Celebrex/Coumadin interaction
- minimizing contraindication in patients with allergic-type reactions to sulfonamides
- omission of important risk information (i.e. contraindication in patients experiencing allergic-type reactions with aspirin or other NSAIDs, liver and kidney disease, late pregnancy, as well as the possibility of GI toxicity)
- unsubstantiated comparative claims (i.e. stating Celebrex is safer than other NSAIDs in combination with Coumadin)
- promotion of unapproved new use and dosing regimen (i.e. Celebrex is safe and effective in treatment of acute pain)

Violations also include a four-sided card and a wall chart used as sales aids that are false and misleading as they minimize the importance of Celebrex's contraindication in patients who have demonstrated allergic-type reactions to sulfonamides.

The FDA requested a written response containing an action plan to disseminate corrective messages about the issues to the audiences that received these misleading messages. Pharmacia must also issue a "Dear Healthcare Provider" letter to correct false or misleading impressions and information.

### To our physicians

- Be aware of misleading pharmaceutical information related to Celebrex.
- Review all Celebrex promotional information in your office for above violations.
- Question patients regarding previous allergic-type reactions to sulfonamides, aspirin and other NSAIDs prior to prescribing Celebrex.
- Question patients regarding liver, kidney and GI disorders prior to prescribing Celebrex.
- Use caution in concomitant use of Coumadin and Celebrex.
- Closely monitor prothrombin time if prescribed for patients on Coumadin.
- Instruct patients in possible side effects and to report unusual symptoms.

### Sporanox and Lamisil

On May 9, 2001, the FDA issued a Public Health Advisory to announce important safety-related updates to the labeling of Sporanox (itraconazole) and Lamisil (terbinafine hydrochloride) Tablets. It is important for physicians to be aware of the association of congestive heart failure (CHF) and hepatic adverse events with the administration of these therapies.

The FDA is advising health care professionals not to prescribe Sporanox to treat fungal infections (onychomycosis) in patients who have CHF or a history of CHF. The FDA believes that there is a small but real risk of developing CHF associated with Sporanox therapy. Rare cases of CHF and pulmonary edema have been reported in the post-marketing period in patients treated with Sporanox capsules. Studies show that once the drug was discontinued the negative inotropic effects resolved.

Both Sporanox and Lamisil have been associated with serious hepatic toxicity including liver failure and death. Some cases involve patients who had neither pre-existing liver disease nor a serious underlying medical condition.

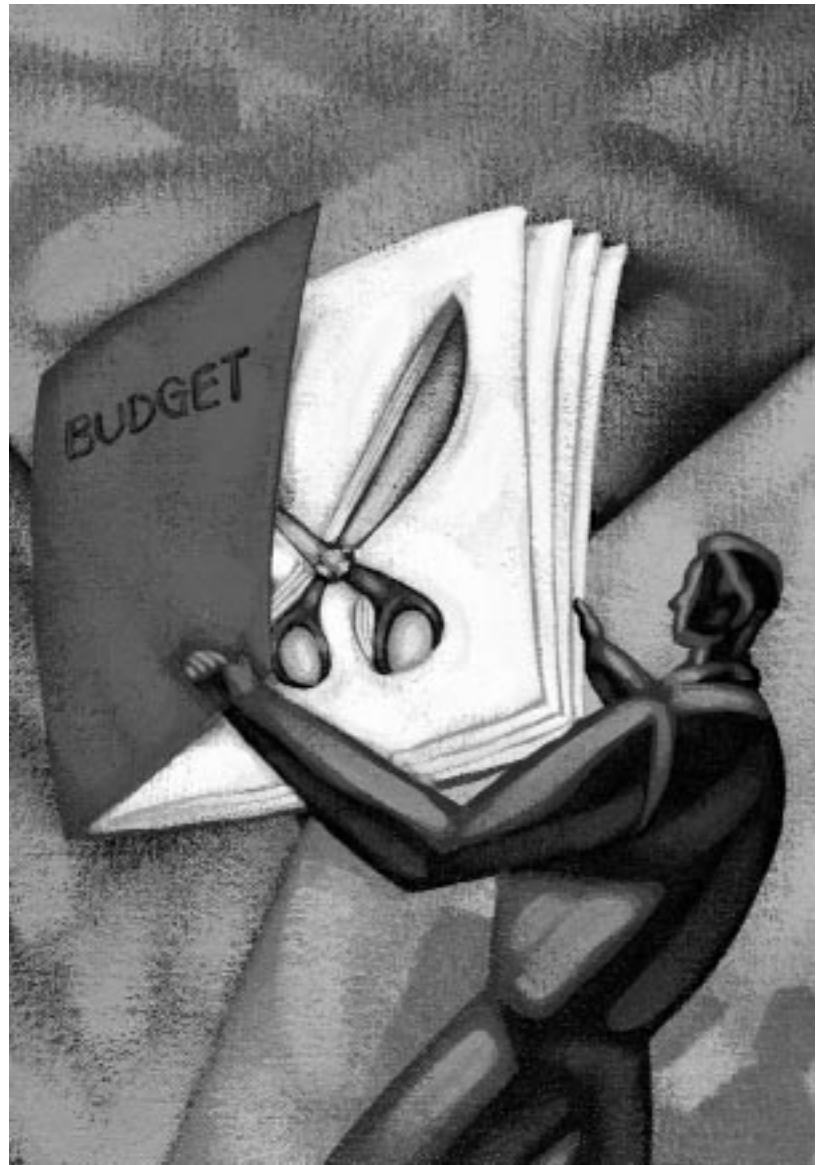
The FDA concerns about hepatic risks associated with the use of Lamisil do not apply to topically applied formulations of terbinafine, such as Lamisil Solution and Lamisil AT Cream.

Janssen Pharmaceutica Products, L.P. and Ortho Biotech Products issued a “Dear Health Care Professional” letter informing providers of the cardiac risks associated with Sporanox therapy, including a package insert with the Boxed Warning.

For more information on these announcements, please contact the FDA at [www.fda.gov/cder](http://www.fda.gov/cder) or Janssen Pharmaceutica Products at [us.janssen.com](http://us.janssen.com).

# The Liability Crisis

*High premiums stretching budgets nationwide.*  
by Laura Hale



The physicians of Texas are all too familiar with the current conditions in the medical liability industry — million dollar jury verdicts, lawsuit abuse, mass litigation, 20, 30 or 40 percent increases in rates for malpractice insurance. Once-entrenched insurance carriers are leaving the state, others are mired with financial difficulties, and serious questions are being raised about the availability and affordability of medical liability coverage. A crisis is looming.

These conditions, however, are not just occurring in Texas. Nationwide, claim frequency and severity are at record levels. Jury awards for malpractice claims jumped 7 percent in one year, from \$750,000 in 1998, to \$800,000 in 1999, according to data from Jury Verdict Research. The 1999 amount represents a 76 percent increase over the 1996 figure of \$454,000. Additionally, about 45 percent of the jury awards in 1998-1999 were \$1 million or more, compared with 39 percent in 1997-1998. These increases occurred even though plaintiffs won 2 percent fewer cases in 1999 than in 1998.

As jury awards increase, so do the costs to settle malpractice claims. In 1999, the national median settlement amount reached \$650,000, a 30 percent increase from 1998.<sup>1</sup>

High damage awards and the resulting malpractice premium increases are stretching the budgets of clinics, hospitals, and physician practices across the country. According to the *Medical Liability*

*Monitor*, liability insurance premiums increased nationally by an average of 14.5 percent in 2000. The newsletter predicts they will increase again in 2001 by an average of 14.6 percent.<sup>2</sup>

The severity of rate hikes varies widely by state and medical specialty, and some states have been hit harder than others. However, the effects are especially apparent in states that lack strong tort reform. Physicians in Pennsylvania and West Virginia are experiencing some of the highest rate increases in the country.

## Pennsylvania

“Our analysis shows that Pennsylvania’s health care system has become like the Titanic. The bow is scraping against an iceberg and we’re all feeling tremors throughout the ship as we take on water. And, yes, like the Titanic, Pennsylvania’s health care system is in serious danger of going under,” said, Carol E. Rose, MD, president of the Pennsylvania Medical Society in testimony before the Pennsylvania Senate.<sup>3</sup>

In addition to purchasing malpractice insurance, physicians in Pennsylvania are required to pay a surcharge to underwrite the Medical Professional Liability Catastrophe Loss Fund (CAT). The CAT fund provides \$700,000 of malpractice coverage, but Pennsylvania physicians are required to carry \$1.2 million as a condition of licensure. The \$500,000 balance must be purchased in the private sector. In 2001, Pennsylvania insurance carriers raised rates from 21 to 60 percent, and the CAT fund surcharge increased from 7 to 56 percent.<sup>4</sup> Increases in CAT fund payments have been attributed in part to the 1998 collapse of two medical malpractice insurers, PIC Insurance Group of Montgomery County and PIE Mutual Insurance Company of Ohio.<sup>5</sup>

Pennsylvania has always been among the states with the highest professional liability costs. According to the Pennsylvania Medical Society, obstetricians/gynecologists who practice in the Philadelphia region pay an average of \$84,000 in malpractice premiums, while ob/gyns in New Jersey pay about \$58,000, and in Delaware, \$52,000. Neurosurgeons pay \$111,000 for coverage in Philadelphia, but \$75,000 in New Jersey and \$58,000 in Maryland.<sup>6</sup>

A main reason for the high rates in Pennsylvania — the state is plagued by huge jury awards and settlements. In 2000, a Philadelphia jury awarded \$100 million verdict against four doctors and two hospitals in a malpractice case involving surgeries and other care for an infant born after 26 weeks gestation. Prior to that \$100 million dollar verdict, Philadelphia juries had returned malpractice awards of \$55 million and \$49.6 million in two other cases.<sup>7</sup>

The number of Philadelphia malpractice verdicts over \$1 million increased 75 percent from 1998 to 1999, putting the state in second place for the highest median malpractice payment in the nation. (New York has the highest.) From 1991 to 1998, aggregate payments made for Pennsylvania physicians and other practitioners increased more than 90 percent from \$193 million to \$370 million.<sup>8</sup>

In response to the conditions in their state, the Pennsylvania Medical Society began lobbying the state legislature for a variety of tort reforms, including a rollback of the constitutional prohibition on damage award caps. Lobbying efforts were intense. On several occasions, hundreds of Pennsylvania physicians shut down their practices and visited the state capitol to lobby for tort reform. Earlier in the year, a dozen orthopaedic surgeons at a Frankford, Pa., hospital decided not to renew their insurance coverage and stopped operating. The move forced the hospital to shut the trauma unit and send patients to other hospitals for four days.<sup>9</sup>

In addition to their lobbying efforts, the Pennsylvania Medical

Society will devote resources to state Supreme Court and other judicial races to ensure a favorable judicial environment for tort reform.

## West Virginia

Physicians in West Virginia are facing a similar situation. Over the past five years, one in two insured physicians were sued in West Virginia, according to data from Medical Assurance, which represents 60 percent of physicians in the state. And while physicians won 85 percent of the suits filed against them, settlements, jury awards and legal fees have driven insurance costs up. According to the West Virginia State Medical Association, average premiums rose 35 percent for all physicians.<sup>10</sup>

Obstetricians practicing in the state pay an average of \$75,000 for liability insurance, while these same specialists pay \$26,000 in Tennessee, \$48,000 in Ohio and \$29,000 in Virginia. West Virginia internal medicine physicians pay an average of \$12,500 per year, while premiums for their colleagues in Kentucky average \$6,400.<sup>11</sup>

To make matters worse, West Virginia’s \$1 million cap on non-economic damages for malpractice claims, the state’s primary tort restraint, has been challenged in the state supreme court twice. It survived the most recent constitutional challenge, but by a slim margin. In the latest case, a jury tried to award a plaintiff \$2.5 million even though West Virginia had a \$1 million cap. The case involved a patient who died from complications following anti-reflux surgery.<sup>12</sup>

In February, more than 1,000 West Virginia physicians and other health care professionals visited the state capitol to discuss the malpractice crisis and the need for tort reform with legislators. The WVMSA will continue to work with legislators to draft reforms, and has launched judicial awareness campaigns.

## The solution

The situation in West Virginia, Pennsylvania and Texas looks even worse when compared with conditions in states that have enacted strong tort reform measures. There is compelling evidence that medical liability reform can protect both physicians and patients.

Long considered the “gold standard” of tort reform legislation, California’s Medical Injury Compensation Reform Act was enacted in 1975 in the midst of a medical liability crisis in the state. MICRA contains several elements, such as a \$250,000 cap on non-economic damages and limits on attorney contingency fees, and has a proven track record in reforming an unruly system and ensuring fair payment to injured patients.

“According to Jury Verdict Research, for the years 1994-1999, the median malpractice jury verdict in Pennsylvania was \$650,000. In contrast, over the same period of time, the median malpractice jury verdict in California was only \$350,000. The difference – California has had meaningful tort reform in place for 25 years,” said Dr. Rose.<sup>13</sup>

Malpractice cases in Philadelphia alone generated more payout in 1998 than did malpractice cases in the entire state of California.<sup>14</sup>

Physicians in California also pay substantially lower rates for malpractice insurance. The average rate for neurosurgeons in Pennsylvania’s highest rated territory is \$111,296, compared with \$58,164 in California — a 50 percent difference.<sup>15</sup>

Physicians in only a few states, including Utah, Colorado and Montana, enjoy this same kind of comprehensive tort reform. More than 25 states have some reforms in place, but statutes are repeatedly challenged in state court, and either scaled back or struck down altogether. Moderate reform measures passed in Pennsylvania in 1996 were overturned a few weeks later by the state’s supreme court. The Illinois Supreme Court in 1997 struck down reforms passed in 1995,



and in 1999, the Ohio Supreme Court completely overturned that state's reforms. Even in California, tort reform advocates must stand ready to defend MICRA reforms from legal challenges.<sup>16</sup>

Absent strong state or federal medical liability reform, conditions in Pennsylvania, West Virginia, Texas and other states will continue to deteriorate. Andrew Wigglesworth, president of the Delaware Valley Healthcare Council in Pennsylvania, summed up the frustration felt by the physicians in his state. "We have virtually none of the tort reforms that other states have . . . We need an equitable system that compensates people fairly but doesn't result in excessive awards that, as a society, we can't sustain."<sup>17</sup>

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# MICRA's basic provisions

## Limits on non-economic damages

Non-economic damages in a claim against a health care provider for medical negligence are limited to \$250,000. Economic damages, such as lost earnings, medical care, and rehabilitation costs, are not limited by statute.

## Evidence of collateral source payments

A defendant in a medical liability action may introduce evidence of collateral source payments (such as from personal health insurance) as they relate to damages sought by the claimant. If a defendant introduces such evidence, the claimant may also introduce evidence of the cost of the premiums for such personal insurance.

## Limits on attorney contingency fees

In an action against a health care provider for professional negligence, an attorney's contingency fee is limited to 40 percent of the first \$50,000 recovered; 33 percent of the next \$50,000; 25 percent of the next \$500,000, and 15 percent of any amount exceeding \$600,000.

## Advance notice of a claim

To further the public policy of resolving meritorious claims outside of the court system, MICRA requires a claimant to give a 90-day notice of intention to bring a suit for alleged professional negligence. If the notice is given within 90 days of the expiration of the statute of limitations, the statute is extended 90 days from the date of the notice.

## Statute of limitations

In California, a claim for alleged medical negligence must be brought within one year from the discovery of an injury and its negligent cause, or within three years from injury.

## Periodic payments of future damages

A health care professional may elect to pay a claimant's future economic damages, if over \$50,000, in periodic amounts. This avoids a claimant's wasting of an award prior to actual need.

## Binding arbitration of disputes

Patients and their health care providers may agree that any future dispute may be resolved through binding arbitration. California statute requires specific language for such contracts and also provides that all such contracts be revocable within 30 days.

# Update on VBAC — Vaginal

by Jane Mueller, Director, Risk Management Department

A trial of labor after previous cesarean delivery has been accepted by the health care community as a method to lower the overall cesarean delivery rate. The American College of Obstetricians and Gynecologists (ACOG) *Practice Bulletin Vaginal Birth After Previous Cesarean Delivery* (Number 5, July 1999) indicated that the cesarean delivery rate in 1995 was high (27.5 percent).<sup>1</sup> Repeat cesarean births accounted for one-third of all cesarean deliveries. The cesarean delivery rate in the US increased from 5 percent to 20.8 percent between 1970 and 1995 without significant reduction of morbidity.<sup>2,3,4</sup>

Improvements in obstetric care made trial of labor following cesarean delivery safer for both mother and infant. However, the concept of VBAC is not universally accepted. In 1981, in conjunction with the National Institutes of Health, ACOG encouraged trial of labor in an effort to decrease the number of repeat cesarean sections.

Despite the numerous citations in the literature, there are no randomized studies to prove across the board that maternal and neonatal outcomes are better with VBAC than with repeat cesarean delivery. Published evidence suggests that the benefits of VBAC outweigh the risks in most women with a prior low-transverse cesarean delivery. However, most VBAC studies have been conducted in university or tertiary-level centers with in-house staff coverage and anesthesia. Few studies have been done which would provide information about VBAC outcomes in smaller community hospitals or facilities.<sup>5,6</sup>

In assessing patients as potential candidates for VBAC, physicians should review the risks and benefits. When VBAC is successful, it is associated with less morbidity than repeat cesarean delivery. The advantages include fewer blood transfusions, fewer postpartum infections and shorter hospital stays.<sup>7,8,9</sup> Most recent studies indicate that

after thorough counseling regarding the risks and benefits. Following discussion with the patient outlining the risks and benefits, consider using a printed informed consent to document the discussion and the patient's understanding of the discussion. (Please see sample on facing page.)

The ACOG bulletin describes candidates and recommendations for trial of labor. Candidates include "most women with one previous cesarean delivery with a low-transverse incision."<sup>12</sup> The bulletin further states a physician should be "immediately available throughout active labor capable of monitoring labor and performing an emergency cesarean delivery."

As indicated above, VBAC is associated with a small but significant risk of uterine rupture.<sup>13</sup> ACOG recommends that a trial of labor should not be attempted where there is an "inability to perform emergency cesarean delivery because of unavailable surgeon, anesthesia, sufficient staff or facility." Such situations may influence the decision to recommend repeat cesarean delivery in lieu of VBAC. Discussions with the patient should be documented and should include information necessary for the patient to make an informed decision.

Since the publication of the bulletin, there has been much debate among obstetricians regarding the criteria recommending that a physician capable of monitoring labor and performing an emergency cesarean delivery be immediately available throughout active labor.

In April 2000, Stanley Zinberg, MD, MS, FACOG, on behalf of the College, issued a statement confirming the need for those institutions offering VBAC to have facilities and personnel immediately available to perform emergency cesarean delivery when conducting a trial of labor for women with a prior uterine scar.

Recognizing the implications such "immediate availability" has for smaller hospitals, obstetricians and the incidence of VBAC in general, the College notes uterine rupture,

## Discussions with the patient should be documented and should include information necessary for the patient to make an informed decision.

major maternal complications such as uterine rupture, hysterectomy and operative injury were more likely for women who underwent a trial of labor than for those who elected repeat cesarean delivery.<sup>10</sup> Although rates could differ based on many variables, the overall occurrence of uterine rupture in women who underwent a trial of labor after a previous low-transverse incision is estimated at 0.2-1.5 percent.<sup>11</sup>

It is reasonable for women to undergo a trial of labor in a safe setting, but the potential complications should be thoroughly discussed with the patient and family and documented. The ultimate decision as to whether to attempt a trial of labor or undergo an elective repeat cesarean delivery should be made by the patient and her physician

although rare, has the potential for significant consequences for both mother and infant. Among these ruptures, the rate of serious maternal and/or fetal morbidity or mortality is 10-25 percent.<sup>14</sup> Since VBAC is an elective procedure, caution needs to be used in assuming this small but significant risk. Dr. Zinberg states, "the operational definition of 'immediately available,' personnel and facilities remains the purview of each local institution, and the College strongly encourages these institutions to make the necessary resources available for eligible patients."<sup>15</sup> Statistically, patient outcomes should improve with the availability of a physician who can immediately perform cesarean deliveries in the event of a complication.

Uterine rupture can occur in spite of excellent clinical

# Birth After Cesarean

care, and those cases are increasingly involved in litigation. It is helpful to the doctor's defense if he/she has documented his or her discussions with the patient, obtained the patient's consent to proceed with VBAC, and been available for an immediate c-section in the event of an unpredictable uterine rupture.

In *Evaluation of Cesarean Delivery* published by the College in 2000, the issues confronting physicians related to VBAC were again addressed. It indicates that in most cases, the cause of uterine rupture in a patient who has undergone VBAC is unknown, but poor outcomes can result even in appropriate candidates with proper management. It also reinforces the need for physicians, anesthesia and other personnel to be available to perform an emergency cesarean delivery in the event of a complication. A number of studies indicate that a VBAC program can be a safe and important component of hospital-based programs to reduce the number of unnecessary cesarean deliveries.<sup>16,17</sup>

Doctors should, whenever considering a VBAC, discuss the risks and benefits with the patient, and document those discussions in the medical record. If the patient chooses to proceed with a trial of labor, then the patient's consent should also be appropriately documented. Please contact ACOG for copies of the above referenced bulletins.

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## SAMPLE

### Informed consent for patients with previous Cesarean birth

1. I understand that I have had one or more prior cesarean(s) with an incision in the non-contracting part of my uterus. \_\_\_\_\_
2. I understand that I have the option of undergoing an elective repeat cesarean or attempting a vaginal birth after cesarean (VBAC). \_\_\_\_\_
3. I understand that approximately 50-80 percent of women who undergo a VBAC will successfully deliver vaginally. \_\_\_\_\_
4. I understand that the risk of uterine rupture during VBAC in someone such as myself, who has had a prior incision in the non-contracting part of my uterus, is around 1 percent. \_\_\_\_\_
5. I understand that in all labors, emergency complications may occur that may not allow sufficient time to operate and prevent the death or injury of my baby. The risk can occur not only in VBAC trials, but also in normal vaginal deliveries. \_\_\_\_\_
6. I understand that the decision to have a VBAC is entirely my own and the option of an elective repeat cesarean has been discussed with me. \_\_\_\_\_
7. I understand that VBAC carries a lower risk to me than does cesarean delivery. \_\_\_\_\_
8. I understand that if I deliver vaginally, I most likely will have fewer problems after delivery and a shorter hospital stay than if I have a cesarean delivery. \_\_\_\_\_
9. I understand that, in a majority of cases where an urgent cesarean is needed, there will still be no ill effects to myself or my infant but occasionally urgent surgery may result in increased blood loss that requires a blood transfusion. In rare cases, the removal of my uterus may be necessary. \_\_\_\_\_
10. I understand that if I choose a VBAC and end up having a cesarean during labor, I have a greater risk of problems than if I had had an elective repeat cesarean. \_\_\_\_\_

*This form has been fully explained to me and I have read the ACOG brochure on VBAC and inquired about any risks or benefits of a vaginal birth after cesarean section. All questions have been adequately answered by the physician and staff.*

Please initial choice:

I want to attempt VBAC \_\_\_\_\_ I want a repeat cesarean section \_\_\_\_\_

Patient's signature \_\_\_\_\_ Date \_\_\_\_\_

Witness' signature \_\_\_\_\_ Date \_\_\_\_\_

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# HEALTH LITERACY

by Barbara Rose, Risk Management Representative

**T**he cornerstone of health care lies within the physician-patient relationship and the level of successful communication developed between the patient and the plethora of health care providers he/she may encounter. How can it be that the following statistics apply to one of the most advanced countries in the world?

## Health care literacy: the numbers

In 1992, the U.S. Department of Education conducted the National Adult Literacy Survey (NALS) to examine literacy in terms of everyday functional tasks.<sup>1</sup> Of the 26,000 American adults interviewed, 15 percent were born outside the United States; the majority with low literacy were white and native born. Among the NALS findings:

- 22 percent of adult Americans are functionally illiterate (they cannot read the front page of a newspaper)
- another 25 percent have difficulty with tasks involving words and numbers (they cannot read a bus schedule)
- approximately 50 percent of Americans have reading and computational skills that are inadequate for them to fully function in our modern society.

A 1995 study by Williams, et al of 2,659 public hospital patients found that:

- 26 percent could not read their appointment slips
- 47 percent could not understand written directions to take medicine on an empty stomach
- 60 percent did not understand the standard consent form
- 21 percent could not understand instructions (for a GI series) written at the 4th grade reading level



- 81 percent of English speaking patients age 60 or older had inadequate health literacy.<sup>2</sup>

A recent study of 3,260 new Medicare enrollees in a national managed care organization found that inadequate health literacy increased steadily with age, from 16 percent of those age 65-69, to 58 percent of those over age 85.<sup>3</sup>

Baker, et al found that individuals with low literacy are twice as likely to report their health as poor and twice as likely to be hospitalized.<sup>4,5</sup>

A study of Medicaid participants found that those reading at the lowest grade levels (0-2) had average annual health care costs of \$13,000 compared with the average for the population studied of \$3,000.<sup>6,7</sup>

The American Academy for an Aging Society estimates that excess health care costs generated by patients with inadequate health literacy

(primarily from extra and longer hospitalizations) is \$73 billion dollars per year.<sup>8</sup>

Among patients who had attended diabetic education classes, less than 50 percent of those with inadequate literacy knew the symptoms of hypoglycemia compared to 94 percent of the patients with adequate literacy.<sup>9</sup>

Risks are apparent and the challenges obvious to health care providers in the establishment of an effective level of communication with patients who have membership in the numbers above. A conscientious commitment to quality care will not be meaningful if each physician cannot identify a patient's level of understanding, adjust teaching accordingly, and then verify the plan of care as comprehended and compliance assured. We expect, and are upset when patients fail to meet our anticipation of complete compliance with

# in the physician's office practice

their plan of care. Today's physician/patient accountability factor on the scales of responsibility will never be equal. However, measures must be taken to ensure patient education methods at appropriate literacy levels and confirmation of learning before leaving the health care environment.

Physicians and other health care professionals must increase their awareness of low literacy and the barriers it creates for the system. How can one determine literacy? It is well known that those with limited literacy are ashamed and struggle to keep it hidden. One study found that 67 percent of patients with low literacy had never told their spouse.<sup>10</sup> The AMA report suggests trying these techniques to aid in verifying patient understanding of medical findings and the recommended treatment plan.

1. Make instructions interactive and use plain language. Have patients do, write, say, or show something to demonstrate understanding. This is referred to as a "teach back" technique.

2. If prescribing medication, have a labeled pill bottle and ask the patient "If this were your medicine, tell me how you would take it?"

3. Have a staff member ask the patient to review the plan of care again before leaving. Adult learners need repetition to remember.

4. Have printed materials including educational handouts, discharge instructions, and consent forms written in simple, ordinary language at 4th-5th grade reading level.

5. Use pictures, diagrams, anatomical models and videotapes where the written word may fail.

While we might want to engage in a heated debate about what is wrong in our schools, both past and present, for the here and now, let us all think pro-actively and strive to enhance the effectiveness of patient education and understanding in the delivery of health care today and every day.

"With new medical knowledge, drugs, treatments, and cost containment measures, today's patients are quickly on their own, with long lists of instructions, medications, appointments, and very little support from skilled professionals. How much of their 'compliance' problems are our responsibility for failing to properly educate and ensure their understanding and ability to carry out the needed care?"<sup>11</sup> The facts and figures are clear! Low literacy equals less compliance and more errors at a time when the health care system in this country continues to react to the provocative November 1999 report of the Institute of Medicine, *To Err Is Human*.

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# tmlt perspective



## The light at the end of the tunnel?

by Howard Marcus, MD, Chairman, TMLT Board of Governors

Skyrocketing medical malpractice awards, class action suits, bankrupt physicians, juries awarding amounts out of touch with reality, and of course increasing medical malpractice premiums to pay for it all. When will this vicious cycle slow down or come to a halt? That's the million (or multi-million) dollar question we're all asking ourselves.

As you are aware, TMLT has shared information with its policyholders explaining the underlying factors of this crisis. We have also made suggestions to physicians and others to talk to legislators, to talk to patients, and to put the spotlight on this unbearable situation any time the occasion arises. We need to get the message out that the legal profession is benefiting at the expense of the consumer, who ultimately pays the price in higher health care costs, if they can afford it at all.

But it's not enough. The time has come to take the dimmer switch off the spotlight and to give this crisis the attention it deserves. I am pleased to report, therefore, that we are in the process of forming a consortium to tackle this problem. The goal of this group is to promote legislation to get this "malpractice liability disease" under control. We are not talking about tort reform as it took place in 1995. While that may have been an attempt in earnest to get a handle on out-of-control litigation, it turned out that its long-term effect on medical liability was minimal. Instead, our group wants to focus on medical liability exclusively and come up with some meaningful reforms, which could result in long term benefits to the patients and to the health care system overall.

Who are the parties that are going to participate in this effort? While the consortium is still in its formative stages, the

discussion has already been joined by the Texas Medical Association, various regional medical societies, insurance and reinsurance carriers, defense attorneys, individual physicians, and associations representing different segments of the health care industry. In addition to getting these organizations around the discussion table, we have also started collecting information from other states in which the malpractice climate is not in the crisis stages like it is in Texas. There is no time to waste. We are only 17 months

away from the next legislative session.

At TMLT we consider medical liability reform one of our highest priorities. As chairman of the Board of Governors, I am proud to be able to play an active role in bringing this effort about. Medical Liability reform goes to the heart of our profession, which is to provide affordable health care to all who need it. Medical Liability Reform will be the main theme of our TMLT Governing Board and I urge your support in accomplishing these important goals.



## Need CME?

Earn CME without leaving your home or office with TMLT's new online risk management course, **Fraud and Abuse Prevention: What Physicians Need to Know.**

Learn about federal and state health care fraud and abuse laws and how to develop a compliance plan to help avoid common errors. This course is currently available at [www.tmlt.org](http://www.tmlt.org).

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TEXAS MEDICAL LIABILITY TRUST

# RISK hot topics MANAGEMENT

## Arbitration agreements

Is an arbitration agreement included in your consent form?

A recent risk management call revealed the need to remind our policyholders to confirm that forms signed by patients do not place the physician in an untenable position.

Although TMLT appreciates physician efforts to manage liability exposures, the use of an arbitration agreement is in violation of the terms of your TMLT professional liability policy under Coverage Agreement B: "The Trust shall have the right and duty to defend any claim or lawsuit brought within the United States of America or Canada seeking compensatory damages against the Named Insured under the terms of this policy, even if any of the allegations of such claim or lawsuit are groundless, false or fraudulent."

In addition, Texas law provides that no health care provider can require or even request a patient or prospective patient to sign an agreement to arbitrate a liability claim unless the form contains a written notice that the agreement is invalid without the signature of the patient's attorney. The notice must be in 10-point boldface type clearly and conspicuously stating:

UNDER TEXAS LAW, THIS AGREEMENT IS INVALID AND OF NO LEGAL EFFECT UNLESS IT IS ALSO SIGNED BY AN ATTORNEY OF YOUR OWN CHOOSING. THIS AGREEMENT CONTAINS A WAIVER OF IMPORTANT LEGAL RIGHTS, INCLUDING YOUR RIGHT TO A JURY. YOU SHOULD NOT SIGN THIS AGREEMENT WITHOUT FIRST CONSULTING WITH AN ATTORNEY. (Texas Civ. Stat. Ann. Art. 4590i, s. 15.01 West Supp. 1998)

## Attorney contacts with physicians

This topic was addressed in a 2000 *Reporter* issue but bears repeating as TMLT's claim and risk management departments are frequently reminded that our policyholders may be contacted directly by an attorney. When physicians receive any calls from attorneys representing a patient or another party or potential party to litigation with a claim against another physician, caution is the key. Bear in mind that both defense and plaintiff attorneys have a client to protect.

Whether a request to "answer a few questions over the phone," "to schedule an appointment at your office to discuss the represented patient with another party as defendant," or "to schedule a deposition," it is unwise to agree to these requests. TMLT advises that our policyholders not engage in these one-on-one exchanges with attorneys without first contacting a representative of the claim department.

Establish a policy for the practice. Educate staff, and follow the procedure as written. Include the name of the attorney/law firm, the plaintiff, the defendant, and determine the nature of the request. Then notify the TMLT claim department of the request and follow the directives given.

Beware of a sense of security or complacency in thinking it harmless to answer a few questions because the claim is not against you. Physicians have on many occasions agreed to a deposition or informally talked with an attorney and subsequently found themselves added to the suit. Once a physician has gone on the record, even with assurances he/she will not be named in the suit, they are often added to the lawsuit. Apologies may be extended by the attorney, but the reasoning will be it had to be done to properly represent the client. There are cases where physicians' comments have been recorded without their knowledge.

Write a policy and procedure for your practice and always notify the claim department if you receive requests of this nature. Allow our staff the opportunity to research the situation and then follow their guidelines.

# closed claim studies

## Failure to perform an adequate exam and alteration of medical records

by Michele Luckie, Risk Management Representative

*The following closed claim studies are based on an actual malpractice claim from TMLT. These cases illustrate how action or inaction on the part of a physician led to allegations of medical malpractice, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. An attempt has been made to make the material less easy to identify. If you think you may recognize your own case, please be assured it is set forth solely for the purpose of assisting and educating Texas physicians. It is our intention to keep confidential any identifying information that is not already part of public record.*

### Clinical presentation

A 56-year-old woman presented to the emergency room complaining of an acute onset of rectal/perirectal pain, worse with bowel movements and sitting. She also had associated bloody discharge with bowel movement and some type of discharge from an area around the rectum. The patient's history indicated medical problems including hypertension, and morbid obesity.

### Physician action

The emergency room physician noted the presence of erythema and external hemorrhoids that were not engorged. He made a final diagnosis of anal fissure and fistula. The patient was discharged to follow up with her family physician the next day.

The patient saw her family physician the following day. There were no charted notes found for this visit. Five months later, this physician signed an Affidavit of No Record for this visit. They were created after the physician was put on notice of this claim, more than seven months after the visit. In these re-created notes, he indicated he examined the patient, found an anal fissure and an external hemorrhoid, and cleared the patient for return to work.

Approximately 36 hours after seeing her family physician, the patient presented to a different emergency room, accompanied by her daughter, with nausea, vomiting, weakness, rectal bleeding and blood sugar of 690

and WBC of 20,000. The emergency room records document a clinical exam showing a 5 x 6 centimeter necrotic area, a large area of erythema surrounding the rectum and a fistula draining purulent debris. She was referred by a colorectal surgeon to a tertiary hospital where a loop sigmoid colostomy and extensive perineal debridement were performed. She was found to have a large area of erythema all around the rectum. A diagnosis of fistula, perirectal abscess and necrotizing fasciitis (Fournier's gangrene) was made.

During a three-month stay in the hospital, the patient had multiple debridements and developed other problems, including diabetes, renal failure and respiratory insufficiency. According to the discharge summary, the patient was fairly stable with the expectation that she could be discharged to a long-term facility in the near future. The patient suffered a sudden hypoxic respiratory event and cardiopulmonary arrest. Due to the nature of her existing medical problems, her daughter, who had durable power of attorney, signed a DNR order and the patient expired later the same day.

### Allegations

- Failure to perform an adequate exam to diagnose necrotizing fasciitis. (The delay resulted in a long hospitalization leading to her premature death.)
- Record fabrication and alteration

### Legal principle

Breach of duty is any violation or omission of a legal or moral duty. The neglect or failure to fulfill in a just and proper manner the duties owed to the patient, such as obtaining past medical history, performing a complete physical exam or appropriate testing, may be found to be a breach of duty which can contribute to allegations of improper performance.

The primary strength of this case was causation. TMLT consultants believed the patient's course would not have been altered had she been admitted to the hospital by the family physician. However, the consultants

found the physician's records to be inadequate and difficult to defend. The re-created records were inconsistent with the development of the patient's disease process. Although the progression of a perirectal abscess to necrotizing fasciitis occurs dramatically and quickly, the common opinion of the consultants was that erythema was noted in the emergency room record. Had the patient been positively diagnosed with erythema, it is difficult to believe there was no erythema or progression of the disease process in the period from the ER visit to the visit with the family physician. The lack of findings on physical exam by the family physician did not appear consistent with the findings 24 hours earlier or 24 hours later. Based on this inconsistency, it was questioned whether a physical exam was done at all.

### Disposition

This case was settled for \$200,000 on behalf of the family physician and \$200,000 on behalf of his practice association. The re-creation of the medical records and the inconsistencies in the re-creation were major factors in the settlement of this case.

### Risk management considerations

Documentation of patient encounters in a timely manner is essential to having a complete and accurate medical record. Every effort should be made to ensure that, by the end of each day, all patient visits have been appropriately charted. The outcome of this case may have been different if the family physician had made a thorough entry in the patient's chart at the time of her visit regarding his examination and assessment. Defense experts felt they had a strong case in support of the physician. This was based on several consultants' review of the case that believed the patient's decline would not have been prevented if she had been admitted a day earlier. It could have been argued that the progression of her condition to an emergent status might or might not have been

*continued on the bottom of page 15*

# Failure to inform and alteration of medical records

by Lynne Dakers, JD, Risk Management Representative

## Clinical presentation

A 36-year old man with a history of excessive sweating on his hands presented to a thoracic surgeon for treatment of his hyperhidrosis. The patient had seen an ad in a magazine in which the thoracic surgeon indicated several treatment options for persons with hyperhidrosis. The patient told the physician the condition had been a life long problem, which affected him socially and professionally. The patient said he had tried numerous medical therapies with no success, and he came to the physician to learn more about sympathectomy.

## Physician action

The physician told the patient what a sympathectomy was and recommended a bilateral T2-T3 thoroscopic sympathectomy be performed. The procedure was carried out by the thoracic surgeon. Postoperatively, the patient developed severe hyperhidrosis of his hands, axillae and feet.

The patient consulted a dermatologist who told him the sympathectomy was irreversible, and he would be combating this condition for the rest of his life. The patient was referred to a neurologist for a second opinion, and the neurologist was unable to help him. The patient then went to see his cousin, a general practitioner, who told the patient he made a mistake in having the surgery.

The plaintiff's expert was critical of the physician's failure to obtain informed consent. One of the physician's own articles on sympathectomy states compensatory sweating occurs. The expert felt this was a significant complication of the surgery and one that required full discussion with the patient.

The plaintiff's attorney made it clear during mediation that he would try to suggest that the physician was, in effect, operating a surgery mill, cranking out dozens of these

operations. In this regard, there is some indication in the record that the plaintiff's attorney intended to make the physician's web site an issue. In addition, there was the magazine ad which had brought the patient to the physician's office.

Further complicating this case was an alteration of the patient's medical chart by the physician. Some time after the surgery occurred, the physician made a late entry on the page referencing the risks and complications involved with the bilateral thoracic sympathectomy.

## Allegations

- Failure to offer other non-surgical treatments for hyperhidrosis.
- Failure to properly inform the patient of the risks and complications involved with the bilateral T2-T3 thoroscopic sympathectomy.
- Alteration of the medical record.

## Legal principle

Informed consent is defined by two legal doctrines — fiduciary relationship and self-determination. Fiduciary relationship requires a physician to inform and advise the patient in an understandable manner of the risks and treatment. Self-determination is the patient's right to agree to or refuse treatment to the extent the law allows. A physician may be liable for damages proximately caused by the failure to obtain informed consent or if the patient does not receive adequate information, which is necessary to make a truly informed decision.

## Disposition

Although the patient in this situation most likely did suffer from compensatory hyperhidrosis, a known complication of this type of surgical procedure, it can be argued that

this type of injury does not have a persuasive visceral appeal to a jury that would have resulted in a large award.

In this particular case, it was principally the alteration of records that weighed against the physician. Because the change in records was expressly to add an indication in the chart that the patient was indeed warned pre-operatively about the very surgical complication he developed, it could be persuasively argued that, since the physician admittedly altered the medical records there is a strong possibility that he did not, in fact, advise the patient of the complication involving compensatory hyperhidrosis or inform him of other non-surgical treatments available.

This case was settled prior to trial for \$250,000 on behalf of the plaintiff.

## Risk management considerations

### Informed consent

The physician's duty to obtain a patient's informed consent prior to a treatment or procedure is his alone and is non-delegable. In order to protect oneself against an allegation of failure to obtain informed consent, physicians must both educate patients as to known complications and alternative forms of treatment as well as document these efforts. With regard to the verbal discussion between physician and patient, the physician should at minimum make a reference to this conversation in his office notes. A suggested method of documentation is:

*Advised patient of the need for ( ) due to ( ). Discussed risks, benefits and alternatives. Patient reviewed educational materials/instructions and states he/she understands and agrees to proceed. It is my judgment that the patient does understand the treatment plan.*

*continued on page 16*

*continued from page 14*

apparent on the day of her visit with the family doctor if the documentation for that visit was not in question.

To make matters worse, the family physician re-created what notes were available for that encounter. After the fact entries may be viewed as alterations to the medical record and can greatly compromise the physician's

defensibility. As was seen in this case, by trying to document a visit that occurred months earlier, the physician only managed to capture a summary of that encounter. The lack of detailed information in the family physician's re-created note raised the question as to whether or not he actually examined the patient. The inadequacy of the chart note became one of the major factors in the decision to settle this case.

Current, complete medical records not only are essential to diagnosis and treatment but can also assist in the defense of a malpractice claim. Charting the information soon after a patient encounter promotes accuracy and completeness of documentation. In addition, the information will be available to you and other members of the health care team.

# the Reporter

TMLT

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## *In memoriam: Robert G. Thumwood, MD*



We are saddened to relay that Dr. Robert G. Thumwood, a family practitioner in Houston, passed away suddenly on July 25, 2001. Dr. Thumwood was a member of the Texas Academy of Family Physicians and a Fellow of the American Academy of Family Practice. He was a past president of Harris County Medical Society.

Dr. Thumwood was one of TMLT's founding fathers, helping launch the fledgling organization in 1979. At that time, he pounded the pavement, going door to door in the medical community to solicit support for the newly formed TMLT. He was elected and served multiple terms on TMLT's governing board and was a past chairman of the board. At the time of his death, he was chairman of the marketing and risk management committees. Dr. Thumwood was a strong supporter of risk management and was continuously involved in the development of risk management for TMLT and its policyholders. We will miss his enthusiasm, his expertise and commitment to service.

*continued from page 15*

In addition to verbal interaction, patient education can take the form of pamphlets, handouts, videos, and pre/post treatment instructions. Any form of patient education should be documented in the medical record to verify the patient was provided pertinent information regarding his/her care and was given information needed to make informed decisions and choices. If your practice routinely provides certain education materials, you may want to consider making a standardized list of such materials to incorporate into patients' charts in order to facilitate documentation. In addition, you may want to consider having the patient sign a form acknowledging that he/she has been provided these materials and has had the opportunity to ask questions.

### Alteration of medical records

Any late entry made into the medical record should be identified as such and include the reason for the lateness of the entry, should reference the date and time of the actual encounter, and should clearly state the date and time of the actual chart entry. Ideally, entries into the medical record should be made contemporaneous with the patient encounter or as soon thereafter as possible. When late entries are made, particularly if they are not identified as addenda, they can be construed as attempts at alteration of the medical record, which can significantly undermine a physician's credibility.

When reviewing a record, especially one involved in litigation (some practices segregate records that are involved in litigation), physicians must be extremely cautious against making any alterations to the original

record, even if they are only attempting to make the record accurately reflect their recollection of events. In this case, the plaintiff's attorney was able to show that an earlier copy of the medical record did not contain the late entry. Even absent such a situation, however, forensic advances in handwriting and ink analysis have made dating of entries quite precise.

### Advertising

Although only threatened by the plaintiff's attorney as an issue, advertising, whether through traditional media such as magazines and office brochures or through a more modern form, such as a web site, can also place the physician at risk. In any form, it is necessary to avoid implied guarantees or any language that may inadvertently cause you to be held to a higher standard of care than required by law.