

the Reporter

The move to electronic medicine

By Jane Mueller, Vice President, Risk Management

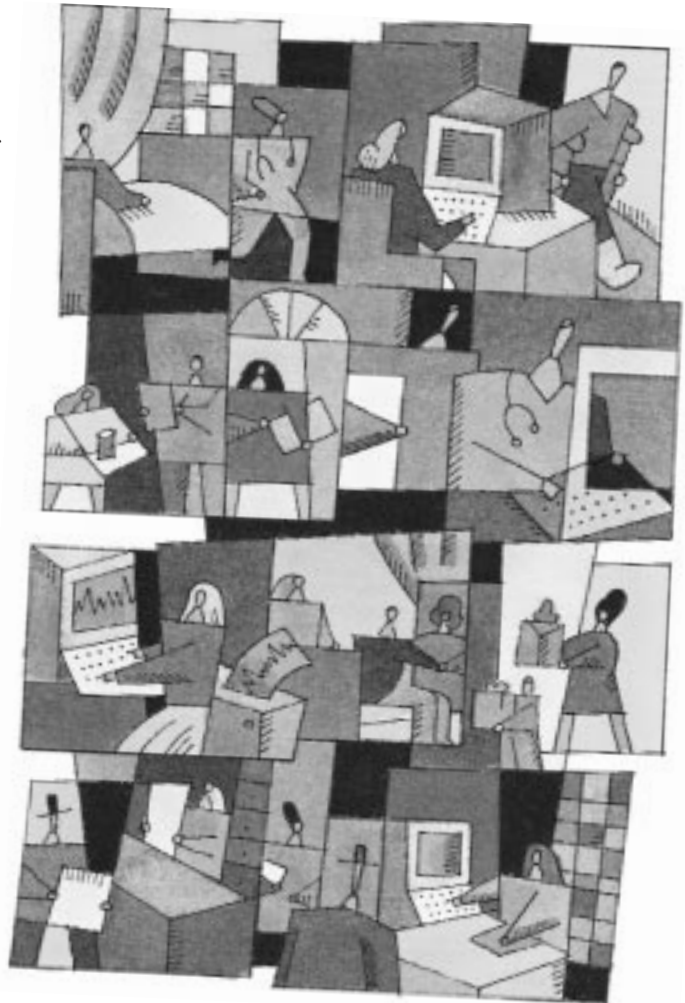
Health care is a \$1.4 trillion industry strangled by paperwork. It is largely paper-based, comprised of hundreds of thousands of separate entities including physicians, hospitals, laboratories, pharmacies and payors. Only 10 percent of health care transactions are now done electronically, lacking the ability to capture, store and access much of that information effectively. The industry is inefficient and remains labor-intensive, with significant duplication of efforts. This problem affects the quality and cost of health care.

It is estimated that 25 percent of all health care dollars is spent on administrative activities. Of the remaining 75 percent, one-fourth is spent on redundant services. It is believed that there are currently \$280 billion in unnecessary administrative and clinical costs.

Much of medicine is routine, requiring compulsive attention to details and protocols. Computers are well suited for these details to enhance medical decision-making.

Physicians are at the center of health care activities. Efficiency and cost concerns are only secondary to quality patient care. An electronic medical record system has the potential to greatly enhance quality of care, providing a safer environment for patients.

By the age of 30, the average person has 11.2 medical records, leading to fragmentation and redundancy. Paper records are difficult to retrieve, review, read and send. They often weaken the defense of a physician in litigation. They are often inadequate in providing a "snap shot" of a patient's condition. There typically is no easy method to retrieve chronic readings such as blood sugar levels or blood pressure measurements. It is difficult, if not impossible, to search patient records regarding drug warnings or recalls. Electronic medical records facilitate contemporaneous documentation as well as immediate availability and retrievability of information. Many systems are



continued on page 2

continued from page 1

designed to provide immediate transmission of medical information from physician to physician or physician to other health care providers. Implementation of electronic medical records in physician offices and hospitals has the potential to decrease medical errors and patient injury, as well as enhancing defensibility.

Data from the Physician Insurers Association of America (PIAA) indicates that medication error is the fourth most common misadventure (i.e. allegation) in medical malpractice claims among all specialties.

Studies have shown that computerized prescription systems have decreased prescription error rates, improving patient safety and saving millions of dollars. Computerized prescription systems attempt to decrease errors by storing detailed databases of all drugs, flagging potentially dangerous drug interactions and preventing physicians and pharmacists from accidentally ordering or delivering drugs in the wrong amounts. They are also sensitive to similarly named drugs and eliminate doctors' notoriously poor handwriting.

The information needed for each script — drug, dosage, quantity, patient instructions, etc. — is electronically selected. Most systems contain formulary information, alerting physicians to drugs "preferred" by patient health plans. Electronic prescribing can be accomplished through use of a personal digital assistant (PDA) or may be incorporated into an electronic medical record system.

As technology continues to improve and evolve, we will witness an expanded role of electronics in medicine including telemedicine and electronic communications, such as e-mail. According to a recent article in *American Medical News*, the generation of 70 million people born between 1977 and 1995 will expect physicians to use the latest technological tools. They will be well educated and knowledgeable about health care and will expect physicians to use e-mail, have web sites, use electronic medical records and have state-of-the-art equipment. For many physicians, the big decision

won't be whether to sign on, but which system to choose. Physicians should evaluate the various systems to determine which one meets their needs.

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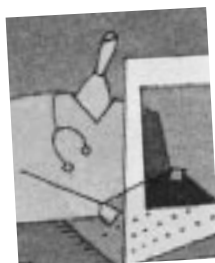
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TMLT introduces electronic medical records discount



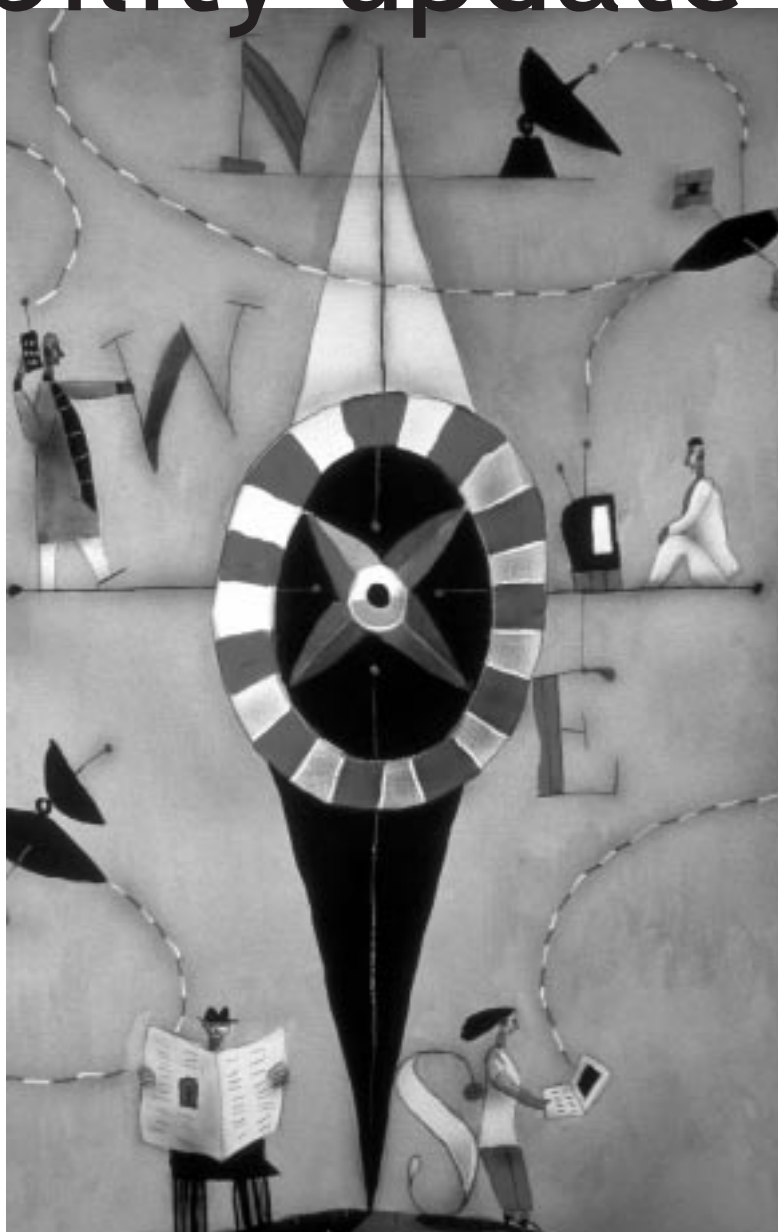
TMLT policyholders are now eligible for a 2.5 percent risk management discount for use of electronic medical records or electronic prescribing. Eligibility for this discount is contingent upon documented use of a program for a minimum of 1 year and must be evaluated by a risk management representative in conjunction with a practice review. The program must also meet specific risk management criteria.

Please contact the Risk Management Department at 800-580-8658 for further information.

Medical liability update

For the past several months, medical liability has been in the news on all fronts. Between the April 8 Day of Awareness, the Texas House of Representatives Insurance Committee hearing, numerous debates, town hall meetings and press conferences, the issue has received significant attention from the media. Since physicians are now all too aware of the problems in Texas, this article will examine what's happening outside the state.

By Laura Hale



Federal legislation

In late April, a bipartisan tort reform bill was introduced in the U.S. House of Representatives. HR 4600, also known as the Help Efficient, Accessible, Low Cost, Timely Health Care (HEALTH) Act of 2002 was introduced by five Republicans and five Democrats to “improve patient access to health care services and provide improved medical care by reducing the excessive burden the liability system places on the health care delivery system.”

Fashioned after California's MICRA law, the HEALTH Act would:

- establish a standard statute of limitation of three years, with exceptions in the case of a minor
- cap non-economic damages at \$250,000; economic and future medical costs would not be capped
- limit attorney contingency fees
- institute joint (not several) liability
- establish periodic payments for future medical expenses

- set a higher threshold for juries to award punitive damages, limited to the greater of two times the amount of economic damages awarded or \$250,000
- require notice of collateral source payments
- federal law would not supercede state laws already in place that offer greater protection

The American Medical Association, the American College of Obstetricians and Gynecologists, the American College of Emergency Physicians, the American Association of Health Plans, and dozens of other state medical and specialty groups support the bill.¹

The House has passed tort reform legislation six times during the past ten years, but the legislation died in the Senate. The original co-sponsors of HR 4600 include Representatives Jim Greenwood (R-PA), Chris Cox (R-CA), John Murtha, (D-PA), Pat Toomey (R-PA), Jim Moran (D-VA), Colin Peterson, (D-MN), Charlie Stenholm (D-TX), Ken Lucas, (D-KY), Chip Pickering, (R-MS) and Dave Weldon, (R-FL). At press time, 25 other representatives had signed on as co-sponsors, and the bill had been referred to the House Subcommittee on Health.²

For full text of this legislation, please visit <http://thomas.loc.gov>.

As the consideration of federal medical liability reform moves forward, several other states are experiencing significant health care access problems due to limited availability and affordability of medical liability coverage.

Nevada

In response to the medical liability crisis in Nevada, Governor Kenny Guinn established the Medical Liability Association of Nevada in March to provide basic malpractice coverage to physicians who cannot obtain insurance from commercial carriers. The governor called the measure a short-term fix, and said he planned to work with the state legislature on reforms to stabilize the market.³ Physicians, however, have said the program is too costly to be helpful,⁴ and health care access problems have worsened.

American Medical News reports that the University of Nevada School of Medicine

may close if it cannot find affordable liability insurance by June 30. The departure of The St. Paul Companies left the school shopping for a new policy. The medical school has 212 medical students, 250 residents and 400 full and part-time faculty.⁵

According to a series of articles in the *Las Vegas Review-Journal*, most of the 93 ob/gyns who deliver babies in Clark County, including Las Vegas, began turning away newly pregnant patients in early May. The physicians remaining have received hundreds of calls from pregnant women and cannot accommodate those who need care.⁶

Governor Guinn has again stepped in, offering improvements to the Medical Liability Association of Nevada to ease the immediate crisis. The association will offer coverage for prior acts, eliminating the need for physicians to purchase tail coverage from the previous insurer. Guinn says this will make the coverage from the state more affordable for physicians.

The governor announced he would consider calling a special session of the state legislature if the physicians, attorneys and insurance companies could reach a compromise on tort reform. The governor also said he would support a \$250,000 cap on non-economic damages.⁷

Mississippi

In recent years, Mississippi has gained a national reputation for astronomical jury awards and settlements. High-profile cases involving tobacco, asbestos, HMOs and pharmaceutical companies have been brought to the state.⁸ Add medical liability to the list. In the first three months of 2002 alone, juries in Mississippi awarded more than \$27 million in medical malpractice cases.⁹

All this has led to an exodus of medical liability insurers. Since 2001, 14 insurance companies have stopped offering medical liability coverage in Mississippi, and only one company is currently issuing new policies.¹⁰ As the remaining carriers raise rates and restrict coverage, physicians are limiting their practices and leaving the state. State health officials told the Associated Press the liability crisis could “doom” Mississippi’s statewide trauma care system and threaten the state’s improvement in infant mortality rates.¹¹

Physicians in Mississippi have lobbied for medical liability reform, including a rally at the state capital, but reforms failed during the 2002 legislative session. Mississippi Governor Ronnie Musgrove says he will call a special session this summer to address the insurance crisis, but wants to steer the issue away from civil justice reform.¹²

Pennsylvania

After a lengthy and bitter legislative battle, the Pennsylvania General Assembly passed a medical liability reform bill in March. The legislation included changes to the civil court system, provisions to improve patient safety, and the privatization of the state’s Medical Professional Catastrophe Loss Fund (CAT Fund). The tort reform measures included requiring the payment of future medical costs in excess of \$100,000 over time, prohibiting patients from suing for damages that were paid by insurance, and requiring patients to bring a lawsuit within seven years of the treatment and within two years after the discovery of the injury, except in cases involving children.¹³

The final legislation was a compromise between a House bill that included caps on non-economic damages and provisions on where a lawsuit could be filed, and a senate version which had been “gutted” of tort reform provisions. The 2002 legislation was Pennsylvania lawmakers’ third try at medical liability reform. Laws passed in 1975 and 1996 were struck down by the state supreme court.¹⁴

Legislative staffers told the *Philadelphia Inquirer* that the reform package would save physicians 10 to 20 percent on their liability premiums over the next several years.¹⁵ Representatives from the Pennsylvania Medical Society offered qualified support for the legislation, and said it was a “positive step forward,” that only “begins to address” the liability problems in Pennsylvania. “We would have liked to see a cap for non-economic damages. This bill contains none,” said Pete Anchor, spokesperson for the society.¹⁶

Following the passage of the medical liability reform package, the Philadelphia-based foundation Pew Charitable Trusts announced it would spend \$3.2 million over two years to create a nonpartisan malprac-

tice project. The goal of the Project on Medical Liability in Pennsylvania is to study the malpractice system and develop long-term policy solutions. The project will first study the impact of the 2002 legislation and then research ongoing medical, legal and economic elements of malpractice.¹⁷

West Virginia

In October 2001, West Virginia Governor Bob Wise convened a special session of the state legislature to consider solutions to the liability crisis. After nearly six weeks of debate, HB 601 was passed. The major components of the bill include a tax credit to assist with the affordability of liability coverage, expansion of the Board of Risk and Insurance Management to allow coverage for physicians who cannot find coverage in the commercial market, a provision to encourage the start-up of a physician's mutual insurance company, the creation of a Joint Underwriting Association and medical liability reforms. Reform provisions include requiring a notice of claim and certificate of merit 30 days before the filing of a claim, time standards for claim handling and medical records requests, and prohibiting third party bad faith claims.¹⁸

While Governor Wise and West Virginia lawmakers expect the legislation will ease the crisis, the West Virginia State Medical Association said “. . . under the current environment, the end product is as much as was politically achievable. Regarding tort reform, there is still not enough support to enact the reforms necessary to bring our civil litigation system in line with other states. The reform enacted during the Special Session are modest but important first steps to address our litigious environment.”¹⁹

During the 2002 Regular Session, a number of additional medical liability reform measures were introduced, but did not pass. However, the legislature did commit to studying the issue.²⁰

Opinion polls

Progress is being made in the area of public education on the medical liability crisis, according to a new public opinion poll. The survey found that the majority of those polled believe litigation is one of the primary factors driving up health care

costs and restricting access to care. The nationwide poll of 1,006 Americans was conducted in April 2002 for the Health Care Liability Alliance by Wirthlin Worldwide, and found:

- 78 percent expressed concern that increasing medical liability costs could limit their access to care

- 48 percent believe the number of lawsuits against health care providers is “higher than justified,” compared with 17 percent who said the number of claims is “lower than is justified”

- 71 percent agree that medical liability litigation is one of the primary forces driving up health care costs

- 73 percent of Americans favor a law that would guarantee injured patients full payment for lost wages and medical costs, and place reasonable limits on awards for “pain and suffering” in medical liability cases

- 76 percent of those polled favor a law limiting the percentage a trial lawyer can collect in a settlement or award from a medical liability case.

(Margin of error is +/- 3.1 percentage points at a 95 percent confidence level)

To determine how litigation affects the practice of medicine and the delivery of health care, the coalition Common Good commissioned Harris Interactive to conduct a nationwide survey of health care professionals. Physicians, nurses and hospital administrators were interviewed, and that survey found:

- 96 percent of physicians believe malpractice claims are brought because of adverse results, not medical errors

- 83 percent of doctors said they did not generally trust the system of justice to achieve a reasonable result

- 76 percent feel their concern about malpractice has hurt their ability to provide quality care

- 79 percent of physicians report they order more tests than may be necessary due to fear of malpractice claims

- 74 percent of physicians report they refer patients to specialists more often due to liability concerns

- 41 percent say they prescribe unnecessary medication

- 51 percent report they perform invasive procedures to confirm diagnoses.

For a complete copy of the Fear of Litigation Study, please visit the Common Good web site at www.ourcommongood.com/news.html.

TMLT will continue to monitor medical liability reform efforts on the state and federal level, and will keep physicians informed about this ever-important issue.

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closed claim study

Failure/delay in diagnosis: cancer

by Barbara Rose, Senior Risk Management Representative

The following closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of physicians led to allegations of professional liability, 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 recognize your own case, please be assured it is presented solely for the purpose of emphasizing the issues of the case.

Clinical presentation

A 47-year-old man presented to a large multi-specialty clinic complaining of burning chest pain. Ten years earlier, the patient had undergone a thoracotomy for the removal of a 10 x 5 cm fibrous dysplasia from the fifth right rib.

Physician action

The patient was seen by his primary care physician, who ordered x-rays and a cardiology consult. The x-rays showed a 3.93 x 4.54 cm right hilar mass. A CT was ordered, and the scan was interpreted by the radiologist as a cystic thymoma. The report stated "there is a mass measuring 3.93 x 4.54 cm in the anterior mediastinum. A cystic thymoma seems a very good possibility — a thymoma would be a first consideration — benign or malignant cannot be determined radiographically. Ten percent of thymomas can be cystic rather than solid." The cardiologist referred the patient back to the primary care physician because the chest pain was not cardiac.

The primary care physician felt the appropriate course of action was to monitor the mass by x-ray for evidence of growth. A chest x-ray taken 6 months later was interpreted to show no change in the mass.

The patient returned less than a month after the second x-ray, complaining of chest pain. He was seen by another primary care

provider in the practice. The second physician felt the chest pain was due to overexertion, as reported by the patient. Six months later, the patient returned for symptoms of poison ivy, and was seen by a third physician in the practice. Three months later, the patient's primary physician saw the patient for symptoms of the flu. The next month, the patient returned with complaints of mid-sternal chest tightness. The primary physician ordered an upper GI, which showed a small hiatal hernia. This was the patient's last visit with the primary physician. It was later discovered that the primary physician made a late entry into the chart for this visit after receiving a notice of claim letter. "See cardiologist if continues" was added in an attempt to show that he referred the patient to the cardiologist if his symptoms persisted.

Over the next year, the patient returned and was treated by the second physician for symptoms including allergy, persistent cough, chest pain and puffy eyelids. Approximately 27 months after the initial x-ray revealed the mass in the patient's chest, he presented with significant swelling in his neck. A CT scan was ordered and revealed substantial growth in the chest mass to 11 x 8 cm. There was significant displacement of the superior vena cava. The patient was referred to a cardiologist who performed a CT guided biopsy that revealed the patient had Non-Hodgkin's lymphoma, large cell type, B-cell origin. Surgical resection was not an option.

The patient was sent for chemotherapy, radiation and eventually underwent a stem cell transfer. The patient's cancer had metastasized to his pancreas, liver, kidney and left femur.

Allegations

Allegations against the two physicians and the clinic include:

- failure to diagnose/treat Non-Hodgkin's lymphoma
- failure to perform appropriate tests, including a biopsy that would have led to earlier diagnosis
- failure to ensure continuity of care
- vicarious liability for the acts of the defendant physicians

Legal implications

Overall, expert consultants were critical of the primary physician's actions in this case. Specifically, it was felt that monitoring a tumor with chest x-rays did not meet the standard of care. Most experts felt the mass should have been biopsied or the patient referred to another specialist to determine how the mass should be followed.

Consultants were divided in their evaluation of the treatment rendered by the second physician. This physician treated the patient five times and did not note the CT scan report. However, it was noted that on all but one of those visits, the patient made no complaints and was experiencing no signs or symptoms related to his chest mass.

Additionally, the second physician was not the patient's primary care physician, and therefore did not have responsibility for his overall medical care.

Consultants were concerned however, about the continuity of care received by the patient and the quality of record documentation by the various physicians. During the time he was treating the patient, the second physician did not communicate with the primary physician at any time about the patient's care. One expert stated that the primary care physician's decision to follow the mass with x-rays was appropriate, but that the care at the clinic fell apart when x-rays were not continued to document the mass.

continued on page 10

RISK hot topics MANAGEMENT

Botox[®] parties — a new wrinkle

In 1989 Clostridium botulinum toxin, purified and transformed into the therapeutic agent, Botulinum Toxin Type A, was approved by the Food and Drug Administration (FDA) for use in treating two eye muscle disorders, blepharospasm and strabismus. In December 2000 the FDA also approved it for treatment of cervical dystonia. Amid cheers from an aging generation of Baby Boomers developing frown lines, forehead furrows and “crow’s feet,” in April 2002 the FDA approved yet another use of the toxin, Botox Cosmetic[®].

This medical treatment involves injecting small doses of the toxin into affected muscles, which acts by blocking the release of the chemical acetylcholine that would otherwise signal the muscle to contract. The FDA Talk Paper states “. . . when used in medical settings . . . [it] paralyzes or weakens the injected muscle . . . because Botox Cosmetic[®] is a prescription drug, it must be used carefully under medical supervision . . .”

While Botox is an approved and widely accepted medical treatment to temporarily improve the appearance of facial lines and wrinkles, it is becoming the latest rage in entertaining. “Botox[®] Parties” complete with hors d’oeuvres and alcoholic beverages, are becoming popular across the nation. Often lured by marketing techniques such as discounted fees for bringing a friend, patients gather in hotels, restaurants and private homes as well as physician offices. When these treatments are performed in casual settings rather than in a controlled medical environment, patient safety is compromised. There may be little opportunity to develop a physician-patient relationship. The drug has worked very well and has had few adverse outcomes; however, physicians need to be cautious in screening patients and administering the drug in a safe, appropriate environment.

Consider the following regarding the appropriate administration of Botox[®] for cosmetic purposes.

- **Use medical offices to perform medical procedures.** The American Society of Plastic Surgeons and American Academy of Dermatology agree casual, social settings, such as Botox[®] parties, are inappropriate for performing medical procedures of any kind. Qualified, trained physicians should administer treatments. Physicians will be held to the degree of learning and skill ordinarily possessed by physicians performing these procedures (i.e. standard of care).

- **Perform a complete history and physical.** Some people may not be good candidates for the procedure.

Some medications including antibiotics, anti-inflammatories, aspirin and even some vitamins and herbal preparations may increase the potency of Botox[®] and may increase bleeding and bruising at the injection site. Pregnant and nursing women should be advised to postpone the procedure as it is unknown whether the toxin has any effect on the fetus or is found in breast milk.

- **Obtain informed consent.** Patients should be advised of the risks, benefits and alternatives of the procedure. Although considered a “safe” procedure, as with any medical procedure there is always the possibility of adverse effects occurring from the botulinum toxin injection, including but not limited to:

- an allergic reaction to the botulinum toxin
- numbness or tingling in the injection area
- swelling or bruising around the injection site
- headache
- nausea
- drooping eyebrow or eyelid (usually temporary but can last 2-3 weeks)
- no improvement in facial lines and wrinkles after undergoing treatment

The informed consent discussion, as well as the patient’s understanding of the procedure, expected outcome, etc, should be documented in the medical record.

- **Be prepared to handle emergencies.** As patients are receiving medical treatment, the expectation is physicians and staffs are prepared to handle an emergency. Basic emergency equipment should be available (i.e. oxygen, ambu-bag with face mask and disposable airways). The office should have an emergency policy and procedure in place and staff should be trained in basic life support.

- **Protect patient privacy and confidentiality.** At best, it would be difficult to protect the privacy and confidentiality of patients in a “party” setting. All patient encounters, discussions and procedures should be conducted in private.

- **Documentation.** In addition to the history and physical and informed consent discussion, the procedure should be documented including the drug, amount of drug, site(s) of injection, patient tolerance/response as well as appropriate post-procedure instructions and follow-up treatments and/or visits.

continued on page 8

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It is difficult to imagine that Botox[®] parties will replace Tupperware[®] parties as the social event of the future. However, as the popularity of this newest form of cosmetic treatment continues to grow, physicians are cautioned to remain astute in their decisions regarding the appropriate setting to provide this service.

FDA prescription drug notices

1. Changes were approved to strengthen labeling for Actos and Avandia. The Warnings, Precautions and Adverse Reactions sections of the labels have been modified. Physicians and their patients with diabetes are alerted to the possibility of fluid retention when either drug is used as monotherapy or in combination with insulin. The fluid retention may lead to, or exacerbate, congestive heart failure. In post-marketing experience, cases of CHF have been reported. (April 26, 2002)

2. Vioxx labeling has been strengthened to describe new cardiovascular and gastroenterological safety information. It should be taken into consideration and caution should be exercised when Vioxx is used in patients with a medical history of ischemic heart disease. (April 11, 2002)

3. Roche Laboratories, Inc., working in cooperation with the FDA, has developed the System to Manage Accutane Related Teratogenicity[™] (S.M.A.R.T.[™]). This system has been developed because data show that despite extensive warnings, pregnant women continue to receive Accutane prescriptions and women continue to become pregnant while taking Accutane. If you prescribe Accutane and do not have copies of the Roche S.M.A.R.T.[™] Guide to Best Practices, request them from Roche or download on the internet from Roche or the FDA web site, at www.fda.gov.

Changes in generic drug substitution laws

The 77th Texas Legislature passed SB 768 which made significant changes to the generic substitution section of the Texas Pharmacy Act. These changes became effective June 1, 2002. Included in the changes are the elimination of the requirement that a prescription be on a two-line form and specifying that the Texas Board of Pharmacy will adopt rules to provide a "dispensing directive" by which the prescriber will instruct pharmacists on substitution instructions. The following are frequently asked questions regarding the new rules.

Under what conditions may a pharmacist substitute on a prescription issued by a Texas prescriber?

The conditions have not changed. A pharmacist may substitute for a brand name product on a prescription

issued by a Texas prescriber if all of the following conditions are met: the generic product costs the patient less than the drug prescribed; the patient does not refuse the substitution; and the prescriber does not prohibit substitution.

How does the prescriber indicate whether or not a pharmacist may substitute on a written prescription?

For written prescriptions, a pharmacist may substitute a generically equivalent drug for the brand prescribed unless the prescriber writes in his/her own handwriting the words "Brand Necessary" or "Brand Medically Necessary" on the face of the prescription.

Since the requirement for the two-line prescription form will be eliminated on June 1, 2002, will there be another required prescription format?

The format is no longer specified. However, the Texas State Board of Pharmacy encourages prescribers who issue written prescriptions in Texas to use a form that contains a single signature line for the prescriber and the following reminder statement on the face of the prescription: "a generically equivalent drug product may be dispensed unless the prescriber hand writes the words 'Brand Necessary' or 'Brand Medically Necessary' on the face of the prescription."

Since a specific prescription format is not required, can a pharmacist dispense the prescription if it is not in the suggested format?

Yes. Pharmacists may dispense a prescription that is not in the suggested format and they are not required to contact the prescriber for substitution instructions.

If the prescriber has written multiple prescriptions on one form and written "brand necessary" on the form, is a pharmacist required to dispense the brand for all of the prescriptions on the form?

No. If a prescriber places multiple prescription orders on one form, the prescriber must clearly indicate which drugs the dispensing directive, i.e. "brand necessary" applies. If the prescriber does not clearly indicate the dispensing directive, the pharmacist may substitute on all prescriptions on the form.

On a written prescription, does the prescriber have any alternative to hand writing the words "brand necessary" or "brand medically necessary", e.g., a rubber stamp, preprinted, check box?

No. The substitution instructions must be manually written on the face of the prescription.

How does the prescriber indicate the dispensing directive on verbal, faxed, and electronic prescriptions?

Verbal/faxed prescriptions:

1. If an order is transmitted orally to a pharmacist, the prescriber or agent may prohibit substitution by

specifying “brand necessary” or “brand medically necessary.” The pharmacist must note any substitution instructions on the file copy of the drug order. If not clearly indicated by the prescriber/ agent that the brand name is medically necessary, the pharmacist may substitute a generically equivalent drug.

2. If the verbal prescription is to be reimbursed through the Medicaid program, the prescriber must clearly indicate that the brand is necessary when the prescription is ordered **and** fax or mail a copy of the original prescription with the words “brand necessary” or “brand medically necessary” on the face of the prescription to the pharmacy within 30 days.

Electronic/faxed prescriptions:

1. To prohibit substitution, the prescriber/agent must note “brand necessary” or “brand medically necessary” on the electronic drug order. If not clearly indicated that the brand is medically necessary, the pharmacist may substitute a generically equivalent drug product.

2. If the electronic prescription is to be reimbursed through the Medicaid program, the prescriber must indicate medical necessity on the order **and** fax or mail a copy of the original with the words “brand necessary” or “brand medically necessary” on the face of the prescription.

Is the pharmacist still required to use the “Orange Book” as the basis for determining if a product is generically equivalent?

Yes. There have been no changes in this portion of the rules. Pharmacists must use FDA’s Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book) as the basis for the determination of generic equivalency. In fact Board rules have been expanded to clarify this issue and now state that pharmacists may only substitute products that are rated therapeutically equivalent in the Orange Book and have an “A” rating. “A” rated drug products include, but are not limited to, those designated AA, AB, AN, AO, AP, or AT in the Orange Book.

Pharmacists may not substitute on any product that has a “B” rating. For example, all levothyroxine products currently listed in the Orange Book are rated BX. Therefore, a pharmacist may not substitute on prescriptions for levothyroxine. In addition, pharmacists may not substitute on products that are not listed in the Orange Book, e.g., Synthroid® or Entex®. In order to change a prescription to a non-A rated product, the pharmacist must contact the prescriber for permission to change the original prescription to a different drug product. If the prescriber approves, the pharmacist must document on the original prescription the authorization to alter the prescription.

Source

www.tsbp.state.tx.us/Newsletter/GenericSub11.htm



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- *How You Can Stay on the Right Side of the Law: Beginning, Maintaining and Ending Physician/Hospital Relationships*
- *Medical Records Handbook for the Physician’s Office*
- *Streetwise*

For more information, please visit the TMLT web site at www.tmlt.org or call (800) 580-8658.

the Reporter

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continued from page 6

Disposition

This case was settled for \$1.8 million on behalf of all defendants.

Risk management considerations

Because the primary care physician in today's health care system is viewed as the director and coordinator of that care, a breakdown in appropriate and timely continuity of care can result in a failure to diagnose and treat. Hindsight, admittedly, continues to be

perfect but the standard of care was not met in this case. The chest CT report stated the mass could not be identified as benign or malignant radiographically. The next treatment choice indicated, according to consultants, should be biopsy.

Alteration of a medical record after notice of a claim breaches proper medical record documentation and will be discovered when a defendant is under oath. A clearly identified addendum or late entry may be written in a timely manner. Any late entry/addendum made in a medical record should be

identified as such and include the reason for the note, reference the date and time of the actual encounter and clearly state the date and time of the added notes.

Never alter a medical record. Once discovered, changing a record seriously damages the credibility of any physician as there is no reasonable explanation for this choice of action.