TMB rules you may not know but should . . . part 2

by Dan Ballard, JD and Stacey Simmons, JD

This is the second in a series of articles about specific Texas Medical Board (TMB) rules that seem to give physicians the most trouble. This article will discuss these more challenging TMB rules in an effort to enhance knowledge of the TMB, reduce exposure to disciplinary actions by the Board, and assist in the physician’s defense should a TMB action occur. In this article, new death certificate requirements, standing delegation rules, and office-based anesthesia rules will be reviewed.

5. New death certificate requirements

Texas physicians who are asked to sign a death certificate must now do so electronically or face fines from the TMB of up to $500 per violation. House Bill 1739 — which took effect in 2007 — requires a medical certifier on a death certificate to submit the medical certification and attest to its validity electronically.

Physicians must register with the Texas Electronic Death Registrar (TEDR) before signing a death certificate. Any physician who signs a paper death certificate because he or she is not registered with TEDR could be fined $500 by the TMB. The Texas Department of State Health Services operates the TEDR.

Physicians should also note that signing a paper death certificate — even if you are registered with the TEDR — is now considered illegal. Therefore, sign up for the electronic system so you will not have to sign a paper death certificate. It is currently taking about two weeks to process a physician’s electronic registration through the TEDR. If you wait and try to sign up after a patient dies, it will be too late and you could be fined.

Though the legislation went into effect in 2007, the TMB began enforcing it in 2011. Although the Board put enforcement on hold in late 2010, they recently restarted enforcement. 

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6. Supervising mid-level practitioners

The rules related to the supervision of mid-level practitioners are focused primarily on requiring written delegation of responsibilities and active follow-through with supervision. The applicable rules are found mainly in Texas Medical Board Rules 185 and 193.6, and the Medical Practice Act, Section 157 (also known as the Texas Occupations Code). All of these rules can be found at the Texas Medical Board web site (http://www.tmb.state.tx.us/rules/rules.php).  

TMB rules require “continuous” supervision of physician assistants, but the rules make it clear that this does not require the physician’s continuous physical presence. The physician must always be available by phone.  

Note however, that Rule 185.16 states that the physician must be on site with the physician’s assistant at least 10% of the time, though there is an exception provided for medically under-served areas. The Medical Practice Act, Section 157.0541, further requires that the supervising physician must review 10% of the charts of mid-level practitioners who are located at a site other than the physician’s primary practice site.  

Regarding documentation of supervision of mid-levels at non-primary sites, Medical Board Rule 193.6(f)(2) requires “If the physician assistant or advanced practice nurse is located at a site other than the site where the physician spends the majority of the physician’s time, physician supervision shall be further documented by a permanent record showing the names or identification numbers of patients discussed during the daily status reports, the times when the physician is on site, and a summary of what the physician did while on site. The summary shall include a description of the quality assurance activities conducted and the names of any patients seen or whose case histories were reviewed with the physician’s assistant or advanced practice nurse. The supervising physician shall sign the documentation at the conclusion of each site visit.”  

Notably, this rule also specifically states that this type of documentation is not required for mid-levels practicing on site at the physician’s primary practice site.  

The Medical Practice Act, Section 157.053 allows for delegation of prescribing authority to mid-levels as long as there is a written standing order or protocol in place that defines the parameters of the prescribing authority. The Act implies that the delegation of prescribing authority should be commensurate with each mid-level practitioner’s experience and expertise.  

Medical Board Rule 193.6 specifies that mid-level practitioners may neither write prescriptions for Schedule II drugs nor write a prescription for more than 90 days for any Schedule III, IV, or V drug. This same rule requires that “A physician shall document any delegation of prescriptive authority to a physician assistant or advanced practice nurse by a protocol, as defined in this section.”  

Medical Board Rule 185.16 limits to five the number of physician’s assistants or their full-time equivalents (up to 50 hours per week) that one physician may supervise. Importantly however, the Medical Practice Act, Section 157.053(e)(1) states that with respect to prescribing practices, the supervising physician may delegate prescription authority to only four physician’s assistants or advanced practice nurses or their full-time equivalents practicing at the physician’s primary practice site or at an alternate practice site. The Medical Practice Act, Section 157.0541(e) also places a limit of four on the number of mid-level practitioners who can be located at non-primary sites of practice of the supervising physician. This would include a combination of both physician’s assistants and advanced practice nurses.  

Any physician who practices in a hospital environment and employs physician’s assistants to help take care of hospitalized patients must consider whether they (the physicians) are sufficiently available to cover acute problems that may be identified by the mid-level practitioner. For example, the question needs to be asked whether it would be appropriate for a surgeon to operate on a patient and then leave town, leaving the mid-level practitioner to monitor the patient and communicate with the physician if problems arise. This arrangement generally works satisfactorily until the need for a second procedure arises. In such a situation, it is necessary to arrange surgical coverage before becoming physically unavailable. In other words, supervision by phone will not always suffice.  

With respect to the requirement for written protocols, Medical Board Rule 185.14(b) states: 

“It is the obligation of each team of physician(s) and physician assistant(s) to ensure that:

(1) the physician assistant’s scope of practice is identified;
(2) delegation of medical tasks is appropriate to the physician assistant’s level of competence;
(3) the relationship between the members of the team is defined;
(4) the relationship of, and access to, the supervising physician is defined;
(5) a process for evaluation of the physician assistant’s performance is established; and
(6) the physician assistant’s annual registration permit is current.”  

Each of these items should be covered in a written document. This same rule also states that “Physician’s assistants must utilize mechanisms which provide medical authority when such mechanisms are indicated, including, but not limited to, standing delegation orders, standing medical orders, protocols, or practice guidelines.” Medical Board Rule 193.6 (f) also requires that “The physician shall also maintain a permanent record of all protocols the physician has signed, showing to whom the delegation was made and the dates of the original delegation, each annual review, and termination.” The important point to keep in mind at all times is that basically all authority of a physician’s assistant is obtained by specific delegation from his or her supervising physician.
An interesting provision of the Medical Practice Act provides at least some degree of protection from liability for supervising physicians. Section 157.060 states “Unless the physician has reason to believe the physician assistant or advanced practice nurse lacked the competency to perform the act, a physician is not liable for an act of a physician assistant or advanced practice nurse solely because the physician signed a standing medical order, a standing delegation order, or another order or protocol authorizing the physician assistant or advanced practice nurse to administer, provide, carry out, or sign a prescription drug order.” The noteworthy aspect of this section is that the legal standard it imposes is whether the physician “has reason to believe” the mid-level practitioner lacked competence, rather than imposing a “should have known” or “should have believed” standard. 14

7. Office-based anesthesia rules

This discussion applies primarily to outpatient, ambulatory, non-accredited clinic facilities that require control of pain or anxiety during treatment by some means other than using local anesthesia or a nerve block. The general purpose of the rule is to first classify procedures into four different levels depending upon the type of anxiolytic, analgesic, or anesthetic being used (either before, during, or after the procedure). The rule then sets forth standards for the level of personnel training and the availability of equipment for each level of care. The rules applicable to this discussion are found in Texas Medical Board Rule 192. 15

First, it may be helpful to give an example of a common situation that illustrates the very broad applicability of this rule. If you give a patient a single tablet of alprazolam to take before removing a mole or performing a cosmetic laser procedure, this rule applies. You will need to comply with the personnel training and resuscitation equipment requirements of the rule. The rules classify this as a Level I situation, which is the lowest of the four levels. In all settings covered by the office-based anesthesia rules, the physician and at least one other person present must maintain certification in basic cardiac life support (BCLS).

Medical Board Rule 192.2(c) provides that in a situation in which a Level I service is being provided, the following requirements must also be met:

“(B) the following age-appropriate equipment must be present:
   (i) bag mask valve;
   (ii) oxygen; and
   (iii) AED or other defibrillator; and
   (iv) epinephrine, atropine, adrenocorticoids, and antihistamines.” 16

Level II services are those in which there is delivery of analgesics or anxiolytics by mouth in dosages greater than allowed at Level I or there is use of tumescent anesthesia. Provision of Level II services requires a higher level of certification of personnel and more sophisticated equipment. For example, the physician must be ACLS (advanced cardiac life support) or PALS (pediatric advanced life support) certified, and there must be an EKG machine and a crash cart available (among other additional requirements). 16

Medical Board Rule 192.4 requires that any physician providing Level II, III, or IV services must register with the Board and pay a fee. 17 Rule 192.2(j) also requires that written protocols must be adopted that cover at least the following subjects:

(A) patient selection criteria;
(B) patients/providers with latex allergy;
(C) pediatric drug dosage calculations, where applicable;
(D) ACLS or PALS algorithms;
(E) infection control;
(F) documentation and tracking use of pharmaceuticals, including controlled substances, expired drugs and wasting of drugs; and
(G) discharge criteria. 18

Management of emergencies. At a minimum, these must include, but not be limited to:

(A) cardiopulmonary emergencies;
(B) fire;
(C) bomb threat;
(D) chemical spill; and
(E) natural disasters. 18

A very important requirement provided by Rule 192.4(l) is that “All equipment and anesthesia-related services must remain available at the office-based anesthesia site until the patient is discharged.” This could easily be interpreted to mean that the physician must remain on site until the patient goes home. 19

Finally, it should be noted that since September 1, 2010, a clinic must be registered with the TMB if the majority of its patients are treated for pain management issues. The specific requirement under Medical Board Rule 195 is for registration if the “majority of patients are issued, on a monthly basis, a prescription for opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone.” 20 The registration forms are available at http://www.tmb.state.tx.us/professionals/physicians/licensed/painManagementClinicRegistration.php

8. Your insurance coverage for regulatory/legal actions arising out of your medical practice

All TMLT policies that cover individual physicians include a Medefense Endorsement, which provides reimbursement for legal expenses for disciplinary proceedings and various audits. Medefense provides coverage for any action by the TMB, a hospital action regarding clinical privileges, actions by the Texas Department of State Health Services or the U.S. Department of Health and Human Services, and non-compliance with Medicare/Medicaid regulations. In addition, reimbursement for individual federal tax audits is covered.
Notify TMLT as soon as you receive the initial letter from the TMB or other disciplinary authority. The policy states that a policyholder has 60 days to report an insured event to receive reimbursement for covered expenses. To preserve coverage, it is extremely important to pay attention to the 60-day window in which to report knowledge of a proceeding.

Retaining an attorney at the very beginning of any regulatory process will allow the attorney to guide you in providing the best response possible. The sooner you involve a TMLT representative in any legal proceeding involving your medical practice, the better your result will be.

Conclusion
With its mission to protect the public and ensure a sufficiently trained physician workforce, the TMB is poised to enforce all rules for which it has responsibility. The practice of medicine is highly regulated and each licensed physician needs to be aware of current TMB guidelines and rules.

Sources


Editor's note
Please note the following corrections to the article “TMB rules you may not know but should . . . part 1.” The article was published in 2011 Volume 2 of the Reporter.

Under the section “Physician advertising,” the advertising rule was cited incorrectly. The correct citation for the rule is 164.6(c), instead of 164.5(c).

On May 5, 2011 — as this article was being published — the TMB changed the language of the advertising rule. The rule now states: “(c) Advertising/Promotion of Goods or Products. Advertising or promotion of goods or products that a licensee sells outside the normal course of business from which the physician receives direct remuneration or incentives is prohibited.” This appears to be a substantial reduction of the previous prohibition regarding the advertising of products for sale. We do not yet have clarification of exactly what this is intended to mean.

Additionally, we have been in contact with the TMB regarding the new rule and we believe that it contains an error that the TMB will remedy in the upcoming months. The error pertains to the new subsection (d) of rule 164.6 that states: “(d) This section applies only to licensees who bill for services provided via the Internet.”

This new subsection could be interpreted to mean that the newly modified advertising rule will apply only if you bill for services provided via the Internet. We have information from the TMB that they did not intend to limit the advertising prohibition in this way. We believe they will remedy this error. The outcome may be that all physicians will be limited to advertising products that they sell in the normal course of business, and no physician may advertise products that they sell outside the normal course of business.

Under the section “Documenting prescriptions,” the TMB rule regarding prescriptions to oneself or family members was stated incorrectly. The rule was quoted as stating:

“The TMB also prohibits the prescription of dangerous drugs or controlled substances for more than 72 hours to oneself, family members, or others in which there is a close personal relationship.”

The words “dangerous drugs or” should be deleted. This rule applies only to controlled substances. All other prescription drugs may be prescribed to self, family, and close personal contacts, as long as such prescribing is not “inappropriate” due to failure in “taking an adequate history, performing a proper physical examination, and creating and maintaining adequate records.”
TrendsMD
Connecting physicians

TMLT has launched a new blog, TrendsMD. It will connect physicians and other professionals who are interested in discussing medical liability issues. A variety of physicians, attorneys, and insurance experts will contribute to TrendsMD.

We invite you to visit the site and add it to your bookmarks. Please feel free to comment on articles that interest you.

Find the site at http://www.trendsmd.com

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- CMS, MAC, RAC, and MIC: what do they mean to me?

Visit http://www.tmlt.org/services/video now to watch these videos.


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Proceed with caution: treating family, friends, and staff

Objectives
At the conclusion of this article the reader will be able to:
1. recognize when the physician-patient relationship begins;
2. identify what the Texas Medical Board (TMB) requires and restricts when treating a family member, friend, or staff member;
3. describe the American Medical Association’s and Texas Medical Association’s position on physicians treating family, friends, and staff; and
4. discuss potential alternatives when asked to treat family, friends, and staff.

Course author
Cathy Bryant is a risk management representative with TMLT.

Disclosure
Cathy Bryant has no commercial affiliations/interests to disclose related to this activity.

Target audience
This one-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

CME credit statement
Under newly revised AMA guidelines, physicians are now required to complete and pass a test following a CME activity, in order to earn CME credit. A passing score of 70% or better earns the physician 1 CME credit. Physicians will be allowed two attempts to pass the test.

TMLT is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. TMLT designates this enduring material for a maximum of 1 AMA PRA Category 1 Credit™. Physicians should claim only credit commensurate with the extent of their participation in the activity.

Ethics statement
This course has been designated by TMLT for 1 credit in medical ethics and/or professional responsibility.

Instructions
You have two options to obtain CME credit from this activity.

Option 1 – online
Complete Reporter CME test and evaluation forms online. After reading the article, go to www.tmlt.org/reporterCME. Click on “Earn CME” under “Proceed with caution: treating family, friends, and staff” (2011 Volume 3). Follow the instructions to complete the test and evaluation forms. Your CME certificate will be emailed to you. Please allow up to 4 weeks for delivery of your certificate.

Option 2 – on paper
Please read the entire article and answer the CME test questions on the paper test forms on page 12. To receive credit, submit the completed test and evaluation forms to TMLT. All test questions must be completed. Please print your name and address clearly. Please allow 4 to 6 weeks from receipt of test and evaluation form for delivery of the certificate.

Questions? Please call the TMLT Risk Management Department at 800-580-8658, ext. 5919.

Estimated time to complete the activity
It should take approximately 1 hour to read this article and complete the questions.

Release/review date
This activity is released on July 15, 2011 and expires on July 15, 2014. Please note that this CME activity does not meet TMLT’s discount criteria. Physicians completing this CME activity will not receive a premium discount.

Introduction
The request seems so simple. A neighbor or friend — who is not a patient — needs something for a common medical problem. You are a physician and you treat medical problems every day. What should you consider before calling in a prescription for that “common medical problem”?

In this article, a “non-patient” is defined as a family member, friend, boyfriend/girlfriend, or staff member for whom no physician-patient relationship has previously been established. It is important to realize that this “non-patient” relationship ends as soon as you begin to assess and treat that “common medical problem” and the relationship instantly changes to a physician-patient relationship.

“If the conversation/interaction at issue had taken place with this person sitting in your exam room, would you have considered it to be a physician-patient encounter? If the conversation were about his sore elbow, then obviously both you and the patient would feel that a physician-patient encounter was taking place.
On the other hand, if the conversation were about health care reform, then neither of you would feel that it was a physician-patient encounter,” explains Austin attorney Dan Ballard.

Additionally, once a physician-patient relationship is established, the physician must meet the requirements of the Texas Medical Board (TMB) for a proper professional relationship.

**What would you do?**

Professional and personal conflicts can arise when you least expect them. Understanding your responsibilities as a physician and responding appropriately in a variety of situations can help you defend your actions if you are facing a TMB complaint or a medical liability suit.

**Family vacation**

You are on a family vacation. Your brother is visiting from out of state. One of his children complains of an earache. Your brother assures you that his son has earaches frequently and the pediatrician prescribes drops and an antibiotic. The closest emergency department (ED) is 45 miles away, but there is a small pharmacy in the town where you are staying. What do you do?

a. Call in a prescription.

b. Call the child’s pediatrician and consult with him before you prescribe anything.

c. Offer to go with the family to the ED to offer support.

d. Tell your brother that there are legal and ethical reasons why you can’t treat his son.

**Small town grocery store**

You live in a small town and you go to the local grocery store. A friend asks you “Hey Doc, what do you think this is?” The friend is pointing to a spot on his arm. What do you do?

a. Examine the spot, tell him that it looks like poison ivy, and suggest he try calamine lotion.

b. Give him your business card and suggest that he make an appointment with you.

c. Tell him to make an appointment with his own physician about the spot.

d. Advise him to go the ED and have the spot checked immediately. You don’t want to take any chances with skin lesions.

**Botox**

You are a plastic surgeon and you want your staff to avail themselves of all the procedures you offer. One Friday afternoon, your receptionist — who has never had any procedures done — tells you she would like to try Botox. What do you do?

a. Instill the Botox injection as she requested. The good results will be free advertising.

b. Tell her that she needs to review the policy and procedure manual and follow the procedures outlined there before you can give her any Botox injections.

c. Suggest that she read the Botox brochure and discuss it with you next week.

d. Have the receptionist complete all your new patient paperwork, including consents. Complete a full assessment and have your full, informed consent discussion. Proceed with her request.

**Sick employee**

You are a solo practitioner with one medical assistant (MA). Your MA comes to work on a busy Monday, looking ill. She believes she has strep throat and asks you to give her a shot of penicillin. What would you do?

a. Ask her if she’s allergic to any medications and then give her the appropriate antibiotic.

b. Suggest she call her own doctor for a prescription for an antibiotic.

c. Have her complete your usual new patient paperwork, assess her, do a rapid strep test, and make a decision on how to treat her.

d. Send her home. No matter how busy it is, you do not want an employee spreading germs to patients.

**Informal care**

Concerns about “informal care” include a range of patient safety issues. “Informal care tends to bypass standard routines, safety checks, and supervision. The exam and diagnosis may have provided the patient with a false sense of security. In the case presented by doing the favor, the physician bypassed usual routines and documentation and the patient did not get the usual education and follow up that should be expected. There is a risk for misdiagnosis and lack of scheduled follow up as well. When informal care occurs, another potential safety issue is the failure to document care or follow protocols.”

Additional risks include:

- “reluctance to obtain or provide a complete medical history
- reluctance to obtain or submit to a complete medical examination
- diagnosis and treatment beyond provider specialty, knowledge, expertise, or competency
- loss of patient privacy and confidentiality
- lack of objectivity on the part of patient or provider
- under- or over-treatment related to “wishful thinking,” hurried/informal nature of encounter, hypervigilance, or other factors
- circumvention of beneficial education and/or procedural protocols
- impaired or inadequate patient education
- lack of documentation
- inadequate or absent follow up.”
Research published in *JAMA* found that 85% of residents say they have written prescriptions for someone who was not a patient, and up to 95% of those residents said they would do the same given special circumstances. Surprisingly, only 4% acknowledged that they were aware of federal and state laws addressing prescriptions in informal care.³

**TMB rules**

Physicians who acquiesce to requests from friends or family members must do so cautiously. What follows is an explanation of the TMB rules that physicians risk violating when treating family, friends, and staff.⁴

**Section 190.8 — Practice inconsistent with public health and welfare**

As related to treating family, friends and staff, a physician may be found in violation of “failure to practice in an acceptable professional manner consistent with public health and welfare” for:

- “failure to treat a patient according to the generally accepted standard of care;”
- “negligence in performing medical services;”
- “failure to use proper diligence in one’s professional practice;”
- “failure to safeguard against potential complications;”
- “failure to disclose reasonably foreseeable side effects of a procedure or treatment;”
- “failure to disclose reasonable alternative treatments to a proposed procedure or treatment;”
- “failure to obtain informed consent from the patient or other person authorized by law to consent to treatment on the patient’s behalf before performing tests, treatments, or procedures;” and
- “prescription or administration of a drug in a manner that is not in compliance with Chapter 200 of this title (relating to Standards for Physicians Practicing Complementary and Alternative Medicine) or, that is either not approved by the Food and Drug Administration (FDA) for use in human beings or does not meet standards for off-label use, unless an exemption has otherwise been obtained from the FDA.”⁵

**Section 190.8 — inappropriate prescription of drugs**

The TMB prohibits the prescription of any drug to oneself, family members, or others in which there is a close personal relationship without taking an adequate history, performing a proper physical examination, and creating and maintaining adequate records. Additionally, prescribing controlled substances is prohibited in the absence of immediate need. “Immediate need” shall be considered no more than 72 hours.⁵

**Section 190.8 — requirements for establishing a proper relationship before prescribing**

The TMB prohibits a physician from prescribing any drug without first establishing a proper professional relationship with the patient. Under TMB rules, to establish a proper professional relationship with a patient, physicians must meet a minimum of four criteria.

1. Establish that the “person requesting the medication is in fact who the person claims to be.” This may not be difficult if you are treating your family, friends or staff.
2. Diagnose “through the use of acceptable medical practices such as patient history, mental status examination, physical examination, and appropriate diagnostic and laboratory testing.” TMB rules specifically state that an online or telephone evaluation by questionnaire is not adequate. Meeting these criteria may be more difficult when treating family, friends, and staff. Consider the vacationing brother and the child with an earache. Do you have adequate equipment to complete a physical examination while in a remote location?
3. Physicians are required to discuss with the patient the “diagnosis and the evidence for it and the risks and benefits of various treatment options.” This may be relatively easy to accomplish, but where will this discussion be documented?
4. Ensure availability or arrange coverage for the patient for appropriate follow-up care. What happens when the family member returns home to another state? What can you do to ensure appropriate follow-up care?

In addition to the four criteria, the patient encounter must be documented in accordance with the TMB medical records rule 165.1.

“(a) Contents of Medical Record. Each licensed physician of the board shall maintain an adequate medical record for each patient that is complete, contemporaneous and legible. For purposes of this section, an “adequate medical record” should meet the following standards:

(1) The documentation of each patient encounter should include:
(A) reason for the encounter and relevant history, physical examination findings and prior diagnostic test results;
(B) an assessment, clinical impression, or diagnosis;
(C) plan for care (including discharge plan if appropriate); and
(D) the date and legible identity of the observer.”

Physicians can prescribe without establishing a professional relationship under the following exceptions.

1. A physician can prescribe medications for the partners of established patients if the physician determines that the patient may have been infected with a sexually transmitted disease. The medications must be prescribed to treat the sexually transmitted disease.
2. A physician can prescribe medications to a patient’s family members if the patient has an illness determined by the Centers
for Disease Control and Prevention, the World Health Organization, or the governor's office to be pandemic.  

3. A physician can prescribe to hospice patients if they are supporting a hospice program. Under Section 190.8(1)(L) (ii), "A proper professional relationship is also considered to exist between a patient certified as having a terminal illness and who is enrolled in a hospice program, or another similar formal program which meets the requirements of subclauses (I) through (IV) of this clause, and the physician supporting the program. To have a terminal condition for the purposes of this rule, the patient must be certified as having a terminal illness under the requirements of 40 TAC §97.403 and 42 CFR 418.22."  

4. The TMB allows the prescription of a controlled substance to oneself, family members, or others in which there is a close personal relationship, but only for a period of less than 72 hours. "It's okay to prescribe for emergency circumstances, and that is what the 72-hour allowance is addressing. But it must be for less than 72 hours," says Dan Ballard. (6)

**Disciplinary action**

The TMB can and does discipline physicians for inappropriately treating family, friends, or employees. "The issue frequently seen by TMB disciplinary panels is the prescribing of controlled or dangerous drugs to family members," says Leigh Hopper, public information officer with the TMB.

These activities are often brought to the attention of the board by a physician's former employee or spouse. A simple phone call to the TMB reporting that the physician treated staff members without ever establishing a proper relationship or that the physician prescribed a controlled substance to a family member could open the doors to a full investigation. The board investigator would then request pharmacy records and the medical records from the physician’s family member. Since the care was given informally, there would be no medical record to send. The TMB could interpret this as a violation of Section 190.8.  

**Opinions from organized medicine**

According to the American Medical Association, "Physicians generally should not treat themselves or members of their immediate families. Professional objectivity may be compromised when an immediate family member or the physician is the patient; the physician’s personal feelings may unduly influence his or her professional medical judgment, thereby interfering with the care being delivered."  

The entire opinion can be read on the AMA website; http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion#189.shtml.

The Texas Medical Association Board of Councilors’ statement on treating family members and friends also offers guidance, but it is not congruent with TMB rules. "One of the physician’s primary duties is to alleviate suffering. Thus, it is ethical to treat family and friends. As with all patients, in the course of treating friends and family, a medical record should be maintained; however, in urgent or episodic situations generating a medical record may not be practical or possible."  

The statement continues, "Please note that the legal requirements for Treatment of Family Members and Friends and for keeping medical records exceed the above ethics opinion. See Texas Medical Board Rule 190.8(1) (M). Please consult your own retained counsel for legal advice on this issue. (Modified February 2008)"  

Given the lack of consensus between these two organizations, it is advisable for physicians to follow TMB rules and use sound risk management principles when treating non-patients. Create a medical record of the care given to any person as soon as possible, even in urgent or episodic situations.

**Closed claim study – improper performance**

The following closed claim illustrates how treating a staff member can lead to a medical malpractice lawsuit.

**Presentation**

An ob-gyn obtained additional training to perform gynecological cosmetic and reconstructive procedures, including breast augmentation. The physician’s long-time employee — a 49-year-old woman — told the physician that she wanted to be his first breast augmentation patient. The ob-gyn examined her, took her breast measurements, and provided her with information about breast implants.

The ob-gyn and his family had been close to the employee and her family before this incident. In addition to the employment relationship, the families socialized together.

**Physician action**

Nine days later, the ob-gyn examined the patient again, and completed the informed consent discussion with her for bilateral breast implants to be performed by the infra-mammary approach. The ob-gyn obtained a history and physical, documenting that the patient was healthy, but had an eating disorder and a history of mood dysfunction. The patient requested “total secrecy” for the procedure from the other employees in the office.

The breast augmentation was completed, as requested, on a Sunday in the ob-gyn’s office. Pre-operatively, the patient was given promethazine, clonidine, diazepam and acetaminophen. Only the ob-gyn and nursing staff had knowledge of the procedure. The procedure went well, and the patient was sent home with her husband. She was prescribed diazepam to assist with post-operative discomfort.

Twenty-four hours after the surgery, the patient’s husband reported in a phone call that his wife was experiencing shortness of breath. The ob-gyn sent his nurse to the patient’s home to assess her. The patient reported chest wall pain and had minimal dyspnea. The nurse examined the incisions and helped the patient
take a bath. There was no documentation of this home visit or the nurse’s assessment.

Over the next several days there were frequent phone calls between the patient and the ob-gyn’s nurse. The patient’s shortness of breath was attributed to “panic attacks” by the physician and the patient’s family.

On the fifth post-operative day, the patient was seen by the ob-gyn in the office. She continued to complain of shortness of breath and coughing. Her O2 saturation was recorded as 98%. On the ninth post-operative day, the patient continued to complain of shortness of breath. A chest x-ray revealed a small pleural effusion with no pneumothorax or other lung problem. The patient returned to work 17 days after the procedure.

One day after returning to work, the patient was seen by a plastic surgeon in a neighboring town. The patient complained about the appearance of her breasts and reported dyspnea on exertion. The plastic surgeon examined the patient and found no evidence of wound problems or infection. He ordered a chest x-ray that showed a 10% pneumothorax and fluid at the base of her lung.

The patient was referred to a pulmonologist. His diagnosis was a hemopneumothorax or a resolving pneumothorax with pleural effusion associated with atelectasis. The pulmonologist placed the patient on amoxicillin clavulanate for one week. The patient returned and a chest x-ray showed re-inflation of the pneumothorax, resolution of the pleural effusion, and resolution of the infiltrate.

The patient returned to the plastic surgeon and stated that she was unhappy with the appearance of her right breast. She also complained of pain in the inferior crease of the right breast. The plastic surgeon described the right implant as having “tethering of the pectoralis muscle with the superior pole of the implant appearing to be under the pectoral muscle and the inferior pole to be pinched within the pectoral muscle.” He told the patient that the implant could stay or he could perform a revision of both implants to the pectoral plane. The patient elected to have the revision surgery. During the procedure, the plastic surgeon released muscle tissue attached to the capsule holding the implant of the right breast.

Allegations
A lawsuit was filed against the ob-gyn, alleging that he caused the patient’s pneumothorax and failed to recognize, diagnose, and properly treat the pneumothorax. The patient also alleged that he improperly placed the right implant and that he did not possess adequate knowledge, skill, training, and experience to perform breast augmentations.

Legal implications
The plaintiff’s plastic surgery expert was critical of the surgical and post-surgical care of the patient. He stated that the ob-gyn caused the pneumothorax during the procedure and failed to recognize it, which was below the standard of care. This expert was also critical of the ob-gyn’s lack of training to perform breast augmentations.

The defense argued that a pneumothorax was a recognized complication that can and does occur without negligence. Shortness of breath is not an unusual complaint following breast augmentation surgery. When the patient’s complaints continued, the ob-gyn appropriately ordered a chest x-ray that did not identify a pneumothorax. The defense expert — an ob-gyn who performs breast augmentation procedures in his office using the same anesthesia and procedures as the defendant — testified that the defendant was properly trained and qualified to perform breast augmentations. This was the ob-gyn’s first breast augmentation procedure and it was performed on a Sunday in his office procedure room.

Disposition
Three years after the breast augmentation was performed, the lawsuit against the ob-gyn was dismissed when the court ruled that the plaintiff’s expert testimony was insufficient.

Risk management considerations
When initiating new procedures, those procedures should occur when and where adequate support is available even when attempting to honor a patient’s special request.

Timely assessment of post-operative complaints of dyspnea should be completed by the physician and not delegated to nursing staff. Referral to an emergency department should be considered if the physician is not available to assess significant post-operative complaints. All contacts, phone calls, home visits, and office visits should be documented in the medical record.

This case demonstrates that anyone — even long-time employees and friends — will often seek legal counsel when they believe they have been injured during treatment or surgery. Though this employee was eager to have the procedure and was well informed when she consented, she was dissatisfied with the result and filed suit against the physician.

Scenarios revisited
After a thorough discussion of the issues related to informal care, reflect back on your initial responses to these scenarios. Have your answers changed?

Family vacation
None of the options presented offered a clear best choice. If you chose to call in the prescription, you should make a chart note of your assessment, your diagnosis, and your treatment just as you would for an ordinary patient that you saw in an exam room at your office.

Small town grocery store
This scenario presents several viable options. It would be reasonable to assess, prescribe, and chart in this scenario given that for some disease entities, special equipments and tests are not
required to make the diagnosis. Conversely, if a more thorough history or examination is required, referral is the better option.

**Botox**
“C” is a good choice. Treat employees as you would any patient seeking treatment from you. “B” is also an option if you have a process for treating employees spelled out in your policy and procedure manual. “D” is also a viable option.

**Sick employee**
No matter how busy your office is, it is advisable to send employees home who are ill. If medical treatment is needed, either send them to their own physician or follow appropriate treatment protocols.

**Risk management considerations**
Physicians are frequently asked to treat family members, friends and staff members. Thinking through the issues and establishing your own personal guidelines can make these situations easier to manage. There may be select cases where treating is the best option; however, a physician should consider the following carefully before making the decision to treat.

1. Consider whether treating family, friends, and staff would create exceptions that are in conflict with your professional standards of care. Examples would be treating without completing a physical examination or without diagnostic testing.
2. Consider whether you can be objective when treating this person as a patient.
3. Does your family, friend, or employee need specialized medical care that you cannot provide?
4. Consider HIPAA privacy issues and protect your medical records.

If you decide not to treat a family member, friend, or employee, be prepared to give supportive responses.

1. “That is something you might want to consider talking to your physician about” can express your concern without giving a medical opinion.
2. “There are legal and ethical reasons that make it ill-advised for me to treat you” will allow you to support the patient in other ways, such as referral or going with him to the ED for care.
3. For staff members, physicians may want to consider communicating their guidelines on treatment during staff meetings or in the practice’s policy and procedure manual.

If you decide to treat a family member, friend, or employee, comply with TMB rules.

1. Establish a proper professional relationship as defined by the TMB.
2. Establish and maintain medical and billing records as you would any other patient.
3. Use the same standard of care for these special patients as you would for any patient in your practice. Order diagnostic testing, prescribe medications and treatment, and make referrals as necessary.

To treat or not to treat — that is a question only you can answer. Whether to document whom you treat and what you did should never be a question. At some time during their careers, most physicians will face decisions about whether to treat a family member or friend. Following proper treatment protocols and documenting the encounter should serve as protection for both physicians and patients.

**Sources**
2. Loss of patient privacy and confidentiality is frequently given as a reason for not creating a chart for the patient. For example, the patient does not want the other employees to see the chart. However, according to TMB rules, this is not adequate justification for not properly charting the patient encounter.

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CME test questions

Instructions: Using black ink, read each question, select the answer, and then clearly mark your selection. Under newly revised AMA guidelines, physicians are now required to complete and pass a test following a CME activity, in order to earn CME credit. A passing score of 70% or better earns the physician 1 CME credit. Physicians will be allowed two attempts to pass the test.

Please fax the completed test and evaluation forms to the Risk Management Department, attention Stephanie Downing 512-425-5996. You can also mail the test and evaluation forms to the TMLT Risk Management Department, attention Stephanie Downing, P.O. Box 160140, Austin, Texas 78716-0140. A certificate of completion will be mailed to the address you provide on the CME evaluation form.

This form can also be completed online at www.tmlt.org/reportercme

1. To establish a proper professional relationship with a patient before prescribing, the physician must:
   - a. establish that the person is who he or she claims to be
   - b. conduct an in-person evaluation and state that you are establishing a physician-patient relationship
   - c. diagnose the patient's condition using acceptable medical practices
   - d. discuss with the patient the diagnosis and the evidence for it, the risks and benefits of various treatment options
   - e. arrange for appropriate follow-up care
   - f. all of the above
   - g. a, c, d, and e

2. Patient safety risks associated with treating family members, employees, or friends include the following:
   - a. in providing this type of care, physicians may bypass standard routines
   - b. the exam and diagnosis may provide the patient with a false sense of security
   - c. the patient may not receive the usual education and follow up
   - d. the physician may fail to properly document the encounter
   - e. all of the above

3. If you decide to treat a family member, friend, or staff member, the Texas Medical Board (TMB) requires that you treat the patient in your office.
   - a. true
   - b. false

4. The American Medical Association's opinion on treating immediate family members states
   - a. in general, physicians should not treat themselves or members of their immediate families.
   - b. physicians should only treat family members in emergency situations.
   - c. it is acceptable to treat family members, but only after the physician properly establishes a physician-patient relationship.
   - d. treat the person's immediate need and transfer care to another physician as soon as possible.

5. When asked to treat a family member, employee, or friend, physicians should always use their best judgment and not deviate from standards of practice, even when attempting to meet special requests.
   - a. true
   - b. false

Statement of completion
I attest to having spent ____________ hours in this CME activity.

Physician signature ____________________________________________ Date ____________________

Proceed with caution
CME evaluation form
Please complete the following regarding the article, "Proceed with caution: treating family, friends, and staff."
Please fax the completed evaluation with the CME test questions.

1. The objectives for this CME were met.  ○ Yes  ○ No

2. The material will be useful in my practice.  ○ Yes  ○ No

3. Did you perceive any evidence of bias for or against any commercial products? If yes, please explain.
   ○ Yes  ○ No

4. How long did it take you to complete this learning activity?
   ○ .5 hr  ○ .75 hr  ○ 1 hr  ○ 1.25 hrs  ○ 1.5 hrs

5. On a scale of 1 to 5, with 5 being the highest, how do you rank the effectiveness of this activity as it pertains to your practice?
   ○ 1  ○ 2  ○ 3  ○ 4  ○ 5

6. What will you do differently in your medical practice after reading this article?

7. Suggestions for course improvement are:

8. Suggestions for future topics include:

Contact information
Name ____________________________
Address ____________________________
Phone ____________________________

TMLT policyholder?  ○ Yes  ○ No

Email address (to have your certificate emailed). Please print legibly. We cannot email your certificate if we cannot read your email address. To ensure your certificate is received in your email inbox, please add TMLT to your address book or safe sender list. Otherwise, your certificate may be flagged by your e-mail provider as unsolicited mail or "spam."

Proceed with caution
Failure to recognize medication side effects

by Louise Walling and Laura Hale Brockway, ELS

Presentation

A 33-year-old man was undergoing treatment for schizophrenia and bipolar disorder. In 2003, his psychiatrist — Psychiatrist A — prescribed ziprasidone, an antipsychotic medication. The use of ziprasidone, like other drugs in its category, can be associated with dystonias and other movement disorder side effects.

Two years later, the patient complained to Psychiatrist A that he had developed a tic. Psychiatrist A recommended that he see a neurologist, but no referral was made. Several months passed and the patient again complained of the tic. He was again instructed to see a neurologist. The patient’s last visit with Psychiatrist A occurred in October 2005. The patient requested continuation of ziprasidone, and a refill prescription was given.

In November 2005, the patient came to Neurologist A with complaints of abnormal neck muscle movements.

Physician action

Neurologist A examined the patient and detected mild cervical dystonia (CD). He later testified that — although it is not documented in his chart note for this visit — he told the patient that his twitching and abnormal head and neck movements may have been caused by ziprasidone. According to Neurologist A, they discussed whether to take the patient off the medication to see if the CD symptoms would subside. The patient told Neurologist A that he did not want to stop taking the medication because it was helping control his schizophrenia symptoms. In his deposition, the patient denied that this conversation took place.

Neurologist A ordered an MRI of the head and neck, and the results indicated that the patient had cervical spondylosis and mild stenosis. The patient returned to Neurologist A with continued CD symptoms. The neurologist prescribed lorazepam and metaxalone to assist with relief of the neck muscle tension.

Two weeks later, the patient was seen by a counselor who worked for Psychiatrist B. The counselor documented “neck spasms secondary to football injury” in the patient’s record. Psychiatrist B continued the patient’s medications, including ziprasidone. The counselor saw the patient three times over the next two months and did not document any CD symptoms. The patient also did not inform the counselor that he was seeing Neurologist A.

Three months after his last visit, the patient returned to Neurologist A. He was continuing to experience CD symptoms and was still taking ziprasidone. Neurologist A ordered a series of Botox injections, but this treatment was not effective. Six months passed and Neurologist A referred the patient to a plastic surgeon for further treatment of CD. The plastic surgeon performed a muscle release surgery after detecting an abnormality of the trapezius muscle. The muscle release procedure only provided the patient with minimal relief. In correspondence to Neurologist A, the plastic surgeon noted, “as you know, the patient developed dystonia, possibly as a side effect of the antipsychotic medication he was taking.”

On November 1, 2006, the patient complained to his counselor regarding his movement disorder symptoms. He advised her that Neurologist A did not think the disorder was related to ziprasidone. The counselor noted that the symptoms could possibly be related to ziprasidone, and referred the patient to Neurologist B.

Neurologist B saw the patient on November 14. He recommended a slow withdrawal from the ziprasidone. The patient was seen by Psychiatrist B on December 1. The ziprasidone was discontinued and the patient was prescribed bupropion.

The patient remained under the care of Neurologist B, but he did not do well psychologically after discontinuing ziprasidone. His CD symptoms did not improve. He developed oral facial movements, tongue protrusion, and kicking legs. In June 2007, he underwent right and left frontal craniotomies with placement of deep brain stimulating electrodes. The electrodes improved the dystonia symptoms, but the patient’s psychological status deteriorated.

Allegations

A lawsuit was filed against Neurologist A. The allegations included:

- failure to recognize that the patient’s CD symptoms were related to the ziprasidone;
- failure to take the patient off ziprasidone and communicate with his psychiatrist about the need to stop the drug; and
- failure to disclose to the patient that the continued use of ziprasidone carried a risk of permanent neuromuscular side effects.

Psychiatrist A and the patient’s counselor were also sued.

Legal implications

The plaintiffs offered testimony from credible experts supporting their claims. Additionally, Neurologist B testified that the prolonged use of ziprasidone likely caused the patient’s CD to become permanent.

The defense argued that Neurologist A did not start the ziprasidone, and it is widely known that the medication was beneficial in treating the patient’s psychological condition. It was also pointed out that all drugs in this class carry the same type of risks, and it would have been up to the psychiatrist to make decisions about the patient’s medications. The patient did not want to stop taking ziprasidone and he was not forthcoming to his various treaters about his CD.

continued on page 16
Negligence in performing colon resection

by Louise Walling and Laura Hale Brockway, ELS

Presentation

On June 23, a 37-year-old woman came to the emergency department (ED). Her chief complaints were rectal bleeding and vomiting. She was evaluated by her primary care physician and a gastroenterologist. The gastroenterologist performed a sigmoidoscopy and found a large rectosigmoid tumor. The gastroenterologist’s report described the tumor as being 15 cm from the anal verge with an extension to 25 cm. Biopsies of the mass showed it to be a moderately invasive adenocarcinoma. The patient was referred to General Surgeon A for removal of the tumor.

Physician action

The patient was taken to surgery on June 26. General Surgeon A resected the tumor. In his operative note — which was dictated on August 22 — he stated that the tumor was considerably lower than he expected. However, he was able to remove the tumor and perform a low, primary anastomosis. General Surgeon A also stated in his report that he never saw the patient’s right ureter, and he did not see any evidence of extravasation of urine.

The pathology report showed a large adenocarcinoma of the rectum with extensive positive lymph nodes. The tumor was classified as T3N2, an advanced cancer.

The patient did well postoperatively, and she was discharged on July 3. She was re-admitted on July 5 due to fever. A CT scan showed a pelvic abscess and right hydronephrosis. The patient underwent a CT-guided drainage of the abscess. A urologist took the patient to the operating room and attempted to pass a stent up the right ureter; the stent could not be passed. A retrograde pyelogram showed the leak and obstruction in the right ureter. The urologist placed a nephrostomy tube.

General Surgeon B — a partner of General Surgeon A — was called to the operating room to perform an exploration of the abdomen. He drained the pelvic abscess, took down the anastomosis, and diverted the patient’s colon with a colostomy. The patient was discharged from the hospital on July 24.

On August 3, the patient was admitted to the hospital where she underwent a CT-guided drainage of another abscess. General Surgeon B placed a Mediport for chemotherapy on August 10, and the patient was discharged on August 12. The patient was admitted to the hospital on September 5 for a urinary tract infection. The infection was treated and she was discharged.

On October 18, the patient underwent a right nephrectomy due to the chronic kidney obstruction and subsequent infection. She was discharged on October 22. The patient was next admitted to the hospital by General Surgeon B for removal of the Mediport and an incisional hernia repair. The patient was followed postoperatively by her oncologist and General Surgeon B.

The patient’s oncology records reflect that she underwent radiation and chemotherapy. She is currently cancer free, but maintains the colostomy. Two years after the colostomy was placed, a colon and rectal surgeon attempted to take down the colostomy. The procedure was unsuccessful due to scar tissue.

Allegations

A lawsuit was filed against General Surgeon A, alleging negligence in causing injury to the patient’s ureter. This negligence was alleged to have caused the pelvic abscess and breakdown of the anastomosis, necessitating the nephrectomy and colostomy.

Legal implications

The plaintiff’s expert criticized General Surgeon A for failure to identify the ureters during the procedure and for not taking steps to protect the ureters. He stated that if the ureters could not be located or identified, the standard of care required the defendant to have a urologist place a stent in the ureter to help with identification and to prevent injury.

General surgeons who reviewed this case for the defense stated that the breakdown of the anastomosis and the ureteral injury were both known complications of colon resections. However, they agreed that General Surgeon A should have identified the ureters before proceeding with the removal of the tumor.

The colon and rectal surgeon who attempted to take down the colostomy also reviewed the case. He was not critical of the ureter injury, but did state that he would have recommended that the patient be treated with chemo-radiation before the surgery in an effort to shrink the tumor. The colon and rectal surgeon was critical of the defendant for not completing the operative report until two months after the surgery.

Disposition

Given the documentation issues and the criticisms outlined by the consultants, this case was settled on behalf of General Surgeon A.

Risk management considerations

Timeliness assists in adding credibility to any physician’s documentation. If there is a less than optimal patient outcome, delayed dictation or missing documents may create questions about other areas of patient care. When dictation or other kinds of documentation are not completed until weeks after the procedure, a fair question is, “how can the physician recall the specific details of this case?” If the documentation had been completed more timely, it may have been more detailed, explaining reasons for decisions that later raised concerns. It would be beneficial for any physician to be familiar with the time guidelines for dictating reports at each facility and follow those guidelines.

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Documentation issues compromised the defense of this case. Neurologist A did not document that he felt the patient’s symptoms were related to ziprasidone and that he discussed this possibility with the patient. The patient denied that this conversation took place. In addition Neurologist A failed to document that he advised the patient to see his psychiatrist immediately so that he could decide whether to keep the patient on ziprasidone.

**Disposition**

This case was settled on behalf of Neurologist A. The claims against Psychiatrist A and the patient’s counselor settled on the day of trial.

**Risk management considerations**

A referral was made to Neurologist A to evaluate the reasons for the patient’s abnormal neck muscle movements. He testified that a discussion occurred about the side effects of taking antipsychotic medications (unusual, uncontrolled muscle movements), and that the patient stated that he wanted to continue taking the medication. Documenting this discussion would have been beneficial, and would have mitigated the “swearing match” that followed. Verifying this information in writing to the referring physician would also have been helpful. Record keeping that indicates when a physician has informed a patient about a medication’s side effects, especially when the side effects are permanent, is good risk management.

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