

the Reporter

Potential pitfalls

Risk management for the EMR

By Laura Brockway

By now, many physicians know that issues related to documentation are a leading cause of medical liability suits. For years *the Reporter* has featured closed claim studies and other articles that stress the importance of maintaining proper documentation. And while this edition is no exception, (please see the CME article beginning on page 7) most articles have been written for physicians who use paper records. This article will cover the documentation pitfalls specifically related to electronic medical records (EMRs) and how to avoid them. EMRs come with their own risk management considerations, and as more physicians begin using EMRs, it's important to address these issues.

In 2006, TMLT risk management representatives visited more than 1,700 physicians to help identify liability exposures and suggest methods to reduce risk. The following list is based on their observations and recommendations to physicians using EMRs.



Implement a strict policy regarding passwords and security. Authorized users of an EMR system are given passwords. The system associates the person who enters that password as the author of the entry in the patient's medical record. It is imperative that passwords only be used by the individuals to whom they were assigned.

Staff members should not have access to the physician level of security because that would allow them to add or alter information as if they were the physician. Staff members should have their own passwords and level of security clearance based on their job functions. Again, avoid sharing passwords simply to make the entry of information easier. (TMLT risk management representatives have visited practices where all clinical staff share the physician's password.)

Not all employees need access to the EMR. Some practices limit access to those in direct

continued on page 2

continued from page 1

patient care. Others may allow non-clinical staff to only view (and not enter or edit) information in the EMR. When an employee who had access leaves the practice, delete his or her password immediately.

Ensure patient encounter records are locked. The information entered into the EMR is likely to be more accurate if done immediately after the visit. The date of dictation or date of transcription should be included. The author of each entry must take specific action to verify that the entry is his or hers and that it is accurate. Once a patient encounter entry is completed, the author should sign it and it should be locked in the system. Not all EMRs are set up to perform this task.

If information needs to be added or comments made after the entry has been locked, the new entry should be clearly identified as an addendum with current date, reference to the date being amended, the reason for the late entry, and electronic signature. Anyone who makes changes and addendums should ensure that they are clearly marked as such. Unclear, after-the-fact entries may be viewed as alterations to the medical record, which can compromise the defense of litigation.

Be aware that templates can import old or inaccurate information. Most EMRs have been designed with templates for patient encounters. While these drop-down menus save time, many physicians are not aware that some EMRs re-populate the same data in the templates for each subsequent visit.

For example, a physician sees a patient who has conjunctivitis and this is noted in the “review of systems” section. At the next visit, if the physician does not edit the “review of systems” section, the conjunctivitis is again noted. It will continue to be picked up from the templates, giving the impression that the treatment plan is not working or that the physician is not editing the record.

Conversely, some programs may be set up so that specific complaints default to “resolved” if the physician or the patient does not renew that complaint on the next visit. Notes should be individualized for each patient encounter, and relevant sections reviewed to avoid importing incorrect, redundant, and irrelevant information.

Make sure physician sign off is clear. Another potential weakness identified in some systems — it is not clear to an outside reviewer that the physician signed the record at the end of the visit. While physician signature could most likely be verified somewhere in the system, the note itself needs to be signed. Initiate an electronic signature when documenting patient encounters.

Additionally, some programs do not allow each clinical staff member making entries to authenticate the entry with a signature or initial. It is recommended that each staff member sign or initial all entries in the medical

record or that the EMR “audit trail” be adapted to trace staff entries.

Review orders or emails before signing off with electronic signatures. In conjunction with the previous recommendation, signing an order is an affirmation that the order is correct. Auto-authentication techniques that do not require the author to review the entry should be avoided. Do not “universally” click off on a series of orders or emails without reading them. (A closed claim study involving this issue was published in the July-August 2005 issue of *the Reporter*, available at www.tmlt.org.)

Enable tracking mechanisms. Most software programs include a tracking system to help ensure that patients have completed recommended tests or consultant referrals. However, risk management representatives have visited practices that are not using these systems or have not discovered them. These tracking systems can minimize exposure to allegations of failure to diagnose and can lead to better patient care. Specifically, they can provide ways to:

- verify that the patient keeps the appointment or completes the test;
- confirm receipt of the report;
- prompt a call to the consultant, imaging center, or lab if a report is not received;
- make sure the physician reviews the report;
- communicate the results to the patient;
- arrange for follow up if necessary; and
- document all these steps with dates and electronic signatures.

It is strongly recommended that physicians employ these tracking systems. Additionally, if you are planning to purchase an EMR, do not buy one without a tracking system.

Establish a system to appropriately capture paper and other external clinical documents. Optimally, all paper documents should be scanned into the electronic record for easy accessibility. These documents could include paper records used before implementing an EMR, diagnostic test results, consultant reports, hospital reports, or records from other physician offices. Additionally, a process should be implemented to ensure that, once scanned, the paper documents are properly stored or destroyed.

Alternatives exist for practices working with systems that have limited memory or scanning capability. Since some patients’ previous medical records can be lengthy (hundreds of pages), physicians can review the records, summarize them, and include that information in the patient’s history within the EMR. The original paper records will still be available from the previous physician, if copies are ever required. While scanning a patient’s entire paper record into the system is preferred, we recognize that this is not always possible. The impor-

tant step is to develop a policy for capturing patients' previous medical records and follow it consistently.

Prescriptions are not always captured in the EMR.

E-prescribing can be very helpful if it saves the information as part of the patient's medical record. If physicians who use EMRs are not e-prescribing, prescriptions should be captured by scanning the paper prescription into the EMR or fully documenting the name, dose, quantity, instructions, and refill amount. Documenting only the name of the medication does not meet the documentation guidelines set by the Texas Medical Board. (Please see the CME article beginning on page 7.) The same is true when dispensing sample medications to a patient.

Ensure records are backed up reliably. The HIPAA security rule requires that patient data be backed up to ensure it can be retrieved if a hardware failure or other event occurs. The risk management department has received several calls from physicians whose back-ups failed. One physician lost 600 patient records due to a hardware failure. He had been diligently backing up the data on a regular basis and storing copies off-site. However, when the back-up was set to restore, the data was unavailable. The back-up process that he had been following since the set up of the EMR was not adequately capturing the patient data.

Creating a back-up data set is only the first step. The back-up record must be tested regularly to ensure that all appropriate data are being copied, and that data restoration is possible. Testing should occur for all back-up types, including in-house creation on a removable hard drive or for processes that send the information over the Internet for offsite storage. Even if an EMR vendor is providing offsite back up, physicians are advised to confirm that the data is created appropriately.

Make sure the records are complete when providing printed copies. Many physicians using an EMR do not regularly print a patient record, and they may be unaware that clicking the print button on an EMR does not always provide a complete record. A patient or subsequent treating physician could receive an incomplete record as the result of the EMR printing protocols. If the records request came from an attorney, and that attorney received an incomplete record, this could cause the attorney to accept and file a malpractice claim based on incomplete information.

After printing what one assumes to be a complete record, ask these questions:

- Does the record show the electronic signature and date the physician signed the progress notes?
- Does the record indicate when entries were made by staff, showing their initials or unique identifier?
- Does the record show all lab and consult reports with the physician signature and date indicating timely review?

- Does the record show all medications prescribed, refills authorized, and samples given (if relevant)?
- Are patient consent forms included in the printed record?
- Are patient telephone calls included in the printed record?

In some EMRs, all this information is available on the screen but does not show up on the printed record when the general print button is clicked. It may be necessary to go to phone notes, prescription refills, etc. and print them individually to ensure that they are included in the complete record that was requested. Confirming that a complete record is sent is a prudent risk management practice.

When implementing systems to have a patient's paper records scanned, test the print function to make sure it captures everything from the scanned documents. Items often overlooked include documentation of phone calls or requests for medication refills.

Conclusion

"EMR systems are quickly becoming the new technology tool used by hospitals and practices replacing manual documentation systems. The promise of EMR is a more accurate, legible and comprehensive medical record, available to physicians at the touch of a button."¹ Whether you are purchasing your first EMR system, have just begun to implement one, or have used one for years, following the recommendations in this article may help you reduce risk and enhance the practice of safe medicine.

Sources

1. Findlay D. Authenticating the electronic medical record. *Healthcare Risk Manager*. Volume 12. Number 30. 2006. Available at www.magmutual.com/risk/newsletters.html. Accessed February 12, 2007.

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patient safety news

Breast implant surgery; recent FDA recalls

by Jane Holeman and Barbara Rose

Managing risk related to breast implant surgery

The FDA recently announced that it has approved the marketing of silicone gel-filled breast implants manufactured by Mentor and Allergan (formerly Inamed). This was a complex, multi-faceted decision. The FDA announcement summarized the risks of the surgical procedure and also mentioned the recommendations for post-surgical care. The announcement is available at www.fda.gov/bbs/topics/NEWS/2006/NEW01512.html.

The FDA also offers many resources on the issue of implant risks and benefits and general patient safety. They are available on the FDA's "Breast Implants Home Page" at www.fda.gov/cdrh/breastimplants/.

Specific information from implant manufacturers is available on their web sites: Mentor at www.mentorcorp.com/index-aesthetics.htm; and Allergan at www.allergan.com/site/products/consumers/home.asp?id=silicone_breast_implants.

Both sites offer links to other web sites containing voluminous information, including physician referral tools, "before and after" photographs, and patient information on the risks and benefits of breast surgery. Two key resources are the physician product information and patient product information.

The Mentor "product insert data sheet" is more than 50 pages, and can be found at www.memorygel.com/PDF/PIDS.pdf. It contains detailed instructions to physicians on patient counseling, including the admonition, "Before making the decision to proceed with surgery, the surgeon or a designated patient counselor should instruct the patient to read *Important Information for Augmentation/Reconstruction Patients About Mentor MemoryGel Silicone Gel-Filled Breast Implants*."

Informed consent

The physician labeling in the manufacturer's brochure includes some comments that appear to leave little room for physician judgment regarding patient counseling. The brochure directs physicians to "... allow the patient at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast augmentation surgery."

The manufacturer also directs physicians to document informed consent by stating, "In order to document a successful informed decision process, the patient labeling includes an Acknowledgment of Informed Decision form at the end of the document, which is signed by both the patient and the surgeon and then retained in the patient's file." In addition there is a CME requirement. Surgeons must take Mentor's Device Access Education Course to gain access to the Mentor product.

The Mentor labeling states: "Breast implantation is an elective procedure and the patient must be thoroughly counseled on the risks, as well as the benefits, of these products and procedures. You should advise your patient that she must read the patient brochures for either augmentation or reconstruction, as applicable. You must read the patient brochures in their entirety."

From a legal standpoint, the foundation of any surgeon's informed consent process must be the manufacturer's product labeling, as well as the state mandated consent forms available at [http://info.sos.state.tx.us/pls/pub/readtac\\$ext.viewtac](http://info.sos.state.tx.us/pls/pub/readtac$ext.viewtac). It would be difficult for a surgeon to justify any system of patient education that failed to include the manufacturer's brochure.

Although the brochure is lengthy, it would be advisable to provide each patient a hard copy of the brochure. It is likely that the product manufacturer will make copies

of the patient information available to the surgeons. Surgeons and patients will benefit from using the manufacturer's consent form. A copy of the form should be kept in the permanent patient record.

Follow-up care

In the discussion on postoperative care, the manufacturers advise screening for rupture of the implants with MRI. They recommend that an MRI be done 3 years after the surgery and every 2 years thereafter. The manufacturers are more direct in their advice in the event of an implant rupture by stating that if a rupture or evidence of rupture is found, "... you [the surgeon] should remove the implant and any gel."

Risk management recommendations

- One to two weeks before surgery, give the patient the manufacturer-provided consent form, *Important Information for Augmentation/Reconstruction Patients About Mentor MemoryGel Silicone Gel-Filled Breast Implants*, available at www.mentorcorp.com/pdf/approved/Augmentation.pdf or *Important Information for Women About Breast Augmentation with INAMED Silicone-Filled Breast Implants*, available at www.breastimplantstoday.com/pdf/M1209-02SiliconeAugLabel.pdf.

- After the patient has had time to review the information, provide an opportunity for her to ask questions.

- Have the patient sign the manufacturer-provided consent form.

- Give the patient a copy of the consent form and maintain a copy in the permanent patient record.

- Document that the patient received, read, and acknowledged understanding the manufacturer's consent form.

- Document that the patient had an opportunity to ask questions and stated her

questions were satisfactorily answered.

- Follow the manufacturers' recommendation for patient follow-up.
- Document that the patient was instructed on the manufacturers' recommendations for MRI follow-up at 3 years and every 2 years thereafter.
- Develop a patient notification system for manufacturer recommended follow-up MRIs. Document patient notification in the permanent patient record.
- Follow the manufacturers' printed information, not what the manufacturers' sales representatives tell you.
- Obtain the most current version of the manufacturer's consent forms.
- Stay current on any labeling changes and FDA warnings on adverse events.

These guidelines are suggested practice protocols based upon the current scientific evidence and the known legal environment. Physicians are urged to adopt these protocols, recognizing that physician medical judgment must govern practice decisions.

Other recent FDA actions

It seems safe to say that many physicians and a well-informed segment of the population have experienced confusion and sometimes distrust regarding the actions of the

Food and Drug Administration (FDA) in recent years. Drugs and devices have been approved and then subsequently withdrawn, sometimes in quick succession to the dismay of physicians and patients. As in the case of silicone gel-filled breast implants, the implants were approved, pulled off the market, and then approved again.

How do physicians manage the almost daily reports regarding FDA actions, notices to pharmaceutical companies, alerts, recalls, etc.? Ultimately, the responsibility for keeping up with this information falls squarely on the shoulders of physicians, who may not be given enough information to help patients make informed decisions. With this in mind, the following risk management practices may help avoid patient harm and possible litigation related to the prescription and use of FDA-approved products.

- Physicians need to be proactive and stay informed on a regular basis. If you have not done so, sign up to receive the FDA's MedWatch notices via email or RSS feed. (Visit www.fda.gov/medwatch/ for complete instructions.) MedWatch is the FDA safety information and adverse event reporting program. It provides important and timely information about medical product safety alerts, recalls, withdrawals, and important labeling changes.

- Open all of your mail. While it can be easy to assume that envelope from a pharmaceutical company is junk mail, it could

be a letter describing an important labeling change or withdrawal information. For example, GE Healthcare sent a letter to physicians in December 2006 describing reports on nephrogenic fibrosing dermopathy after imaging studies with Gadolinium.

- Require a comprehensive medical history from your patients including their use of illegal drugs, prescription pain medications, and OTC products (analgesics, vitamins, herbs, weight loss products). Patients may be poor historians or may consider their use of herbal supplements unimportant. (For example, use of St. John's Wort is contraindicated in patients who will be undergoing general anesthesia.)

- Review all current information about drugs, medical products, and devices that are part of your practice. It is unwise to base treatment recommendations on the abbreviated information provided by a marketing representative.

- When discussing treatment decisions and options with patients, remember to include the most current information available along with the known risks. Document this exchange and the patient's informed choice in the medical record.

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Order a copy of *You've Been Sued: Successfully Navigating the Litigation Process.*

This 3-hour DVD CME course is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

Contact TMLT's Risk Management Department at 800-425-5912 or email us at rebecca-henson@tmlt.org.



readership survey

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EXPIRED CME

Dissolute documentation?

TMB rewrites the rules for medical records



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This activity is released on April 2, 2007 and expires on April 2, 2009. Please note this CME activity does not meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.

Objectives

At the conclusion of this educational activity, the physician should be able to:

1. describe the elements of an "acceptable" medical record as defined by the Texas Medical Board;
2. List the requirements for retention of medical records;
3. discuss the guidelines for proper release of a medical record; and
4. apply the TMB guidelines regarding fees allowed for copying and shipping records.

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Disclosure

John Porter and Jane Holeman have 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.

New rules

For years, the Texas Medical Board (TMB) rules regarding medical record documentation merely required that physicians maintain “adequate medical records.” This was defined as “any records documenting or memorializing the history, diagnosis and treatment of any patient.”¹ Recently however, TMB staff determined that this rule was incomplete and failed to convey the importance of the medical record. Believing the rule was far too vague, TMB members insisted that the new rule require licensed Texas physicians to include documentation in the medical records that would not only assist them, but would also be valuable to all physicians subsequently treating the patient. As a result of frustration and the increased perception of inadequate medical records, the TMB radically rewrote the rules defining the requirements for an “adequate” medical record.

This article focuses exclusively on TMB rules and policies as they relate to the physician’s obligation to create an “acceptable” medical record, the physician’s obligation to maintain those records, and when and how to release medical records. This article will assist physicians in understanding how the TMB views the various obligations relevant to medical records.

If it was not documented . . .

In medical school and residency, if you did not hear the phrase, “If it was not documented, it was not done,” you were not paying attention. Board members often repeat this phrase during Informal Settlement Conferences (ISCs), as the medical records they frequently review are sub-standard. The vast majority of “standard of care” investigations that result in an ISC are due largely to poor documentation. Generally, the physician failed to write legibly, document thoroughly, and/or demonstrate a nexus between the diagnosis and treatment. The failure to adequately communicate and document in the record has been a significant issue for numerous physicians who appear before the TMB.

What exactly does the TMB require?

Most physicians incorrectly believe that following the basic SOAP method (Subjective, Objective, Assessment, Plan) is sufficient for the Board. However, it is often insufficient based upon the lack of detail physicians provide in the subheadings of the SOAP method. While SOAP is an accepted and appropriate

method of documentation, the problem lies with the person creating the medical record.

The TMB has long insisted that a medical record serve two distinct and important functions. First, the purpose of the medical record is to memorialize the medical history and patient care provided by the treating physician. Many physicians appearing before the TMB with sparse patient records are able to demonstrate a keen memory regarding the histories and treatments of their patients. They can adequately explain specifically what they did for each patient and why they did it. The clinical care is often explained in a logical manner as being medically appropriate. However, documentation of the care provided is missing in the medical record.

To the TMB, the secondary purpose of medical records is to assist other physicians who subsequently treat the patient. Patients frequently seek second opinions, visit specialists, or choose other physicians. Medical records reviewed by the TMB are often found to be missing adequate documentation (i.e. diagnosis, treatment regimens, and medical decision making) regarding care provided to the patient, and therefore are determined to be of little value to physicians providing subsequent care.

Violations of the rule

The rule governing medical record documentation may be found in either the Texas Administrative Code Section 165.1, or in the Board rules posted on the TMB’s web site.² The Texas Administrative Code is the legal designation for the TMB’s rules. The revised documentation rule is significantly different in nearly all aspects. While it still requires a physician to maintain “adequate” medical records, the TMB has now included specific definitions. This section will describe in detail the new requirements and provide some suggestions regarding compliance with the rule.

The rule states medical records must be “. . . complete, contemporaneous and legible.”³ Therefore, documentation must include complete details for each patient encounter, be created close to the time the physician saw and treated the patient, and be legible to the average person. Many physicians have a difficult time with all three aspects. We will discuss in great detail the meaning of “complete,” but first we will focus on “contemporaneous” and “legible.”

The TMB rule does not specifically define “contemporaneous.” However, by practice, most TMB members emphasize that docu-

mentation should be completed immediately after, if not during, the actual patient encounter. If a physician chooses to complete the records at the end of the day instead of immediately following the patient encounter, it appears that he or she would be in compliance, assuming the physician did not see a considerable number of patients that day. However, many TMB members are of the opinion that the records then become too general, and it is likely the physician may forget relevant information. TMB members generally believe that if the physician had completed the record earlier in the day, the information would not have been forgotten.

Legibility has long been an issue for physicians. The advent of electronic medical records and transcribed records is beginning to have a positive impact. However, for physicians who still hand-write notes, illegibility will likely be viewed by the TMB as a lack of compliance with Board rules. When evaluating standard of care issues, all records are reviewed by at least two TMB consultants. It is essential that these consultants are able to read the records. You do not want them guessing at what you mean.

Use caution when employing medical record templates or preprinted forms that contain “check boxes” to designate systems as normal or abnormal. This includes emergency department records and the forms suggested by Medicaid. These forms are often intended to facilitate documentation by “prompting” the physician to address multiple aspects of the patient encounter. While these forms are an acceptable method for documentation, physicians should be aware that there is a dispute among some TMB members and TMB consultants regarding their use. Often the space for handwritten entries is limited, resulting in illegible notes related to an affirmed check. When using such forms, write legibly and use an additional page to fully describe findings, if necessary.

The Board requires that each patient encounter must be documented and include the following requirements:

- 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.⁴

There is an expectation that an appreciable connection be made between each of the above four requirements, and that the connection is explored and documented. Therefore, there is a desire by the TMB that physicians document the medical rationale for testing, treatment, and prescriptions.

By way of analogy, think about an elementary school math class. It is possible for you to know that 144 divided by 12 equals 12. However, the math teacher requires that you “show your work” to receive full credit for the problem. According to the TMB rule, physicians need to demonstrate how they got from the objective and subjective findings to the diagnosis and treatment. In other words, how you got from Point A to Point B is equally important as simply getting to Point B.

The rule also requires that all past and present diagnoses should be accessible to the physician.⁵ This means all records should be readily available to all physicians treating the patient.

Furthermore, the rationale for and the results of diagnostic testing and other ancillary services should be included in the medical record.⁶ This may even include an explanation of the results and how they affect the treatment of the patient.

The rule also requires that the patient’s progress be documented, including response to treatment, change in diagnosis, and the patient’s noncompliance.⁷ Documentation of noncompliance may exonerate the physician on a standard of care complaint. Defending a standard of care case by alleging the patient was noncompliant is generally ignored if there is a lack of documentation in the record supporting that stance. Many physicians prefer not to document noncompliance fearing that insurance companies or the patient may request the record. Failing to document noncompliance places physicians at odds with the TMB and its rules.

The new rules also require documentation of informed consent. It is the physician’s responsibility to identify risk factors related to treatment.⁸ This should be clearly stated in the medical record. Documentation needs to demonstrate that the physician provided the patient (and/or the patient’s family) with education on the diagnosis and treatment, as well as the risks of any treatment. Board members have been critical of physicians who did not document that the diagnosis was adequately explained to the patient, including the differential diagnosis and the impact on the method of treatment.

Although the rules do not specifically address the issue of a patient signature on a document verifying the discussion, consider having the patient sign a document, with the provision that it states the patient and/or the patient’s family were given an opportunity to ask questions, and all questions were satisfactorily addressed. Allowing time for patients and/or their families to ask questions, with the physician providing appropriate answers, will assist in defending the physician against allegations of failure to adequately inform the patient. Supplying patients with written information, and documenting this with the patient’s or family’s signature is also helpful.

The TMB rules also require an appropriate written treatment plan for patients.⁹ However, the Board fails to define “appropriate.” As the rules are written, this should be included in the “P” (or Plan) section of a SOAP note:

1. treatments and medications (prescriptions and samples) specifying amount, frequency, number of refills, and dosage;
2. any referrals and consultations;
3. patient/family education; and
4. specific instructions for follow up.¹⁰

From experience, the above four requirements are always “appropriate” if any of the four actions are taken. If there is a prescription written and/or samples given to the patient, it must always be documented. Documentation of a prescription or the distribution of sample medications must include:

- patient name;
- number of pills;
- number of refills, including zero if no refills are provided; and
- dosage.

It is important to note that physicians are required to maintain receipts of sample medications received from pharmaceutical representatives. The receipts should include lot numbers.

Referrals and consultations

If the physician determines that a referral or consultation is in the best interest of the patient, the rules require that it be documented in the medical record. It is recommended that the treating physician include a sentence or two describing either the medical necessity or the rationale for a referral and/or consultation. If the patient is referred to a specific health care professional, it is further recommended that documentation include the

reason for that particular referral.

A copy of the referral or consulting physician’s report should be placed in the medical record. Failure to receive and maintain such a report limits the physician’s ability to see the “whole” patient picture. It is your responsibility to follow up on the referral and ensure you receive the report or determine that the patient was noncompliant with the referral. Likewise, the physician to whom the patient was referred needs to have a copy of the patient’s medical record or at a minimum, a summary of the patient’s care provided by the referring physician. The referring physician should also retain a copy of the summary in the medical record.

During ISCs, physicians under investigation are often unable to demonstrate that they have reviewed the records of prior treating physicians and other health care professionals. The TMB rule states that records received from other health care professionals involved in the care of the patient shall be maintained as part of the patient’s medical records.¹¹ This means that physicians are required to maintain not only the records they create, but also those they have received from other physicians and health care professionals. If you have a complex patient with multiple sets of records, you are required by TMB rule to maintain those as if they were your records.

Patient education

Documentation of patient education will demonstrate the informed consent discussion about diagnosis, treatment (including medications) and risks; that the physician provided time for discussion between the patient and/or family; and that their concerns were addressed. It is recommended that details of patient education be included in the documentation. There have been instances in ISCs where a physician has written nothing more than “patient education” in the medical record. In those situations, the Board has emphatically told the physician that his or her documentation was inadequate. TMB members require that the documentation provide some indication of what was discussed and how the patient was educated.

Following are some suggestions that may assist in providing patient education. While they may seem beyond the standard of care, it is likely they will assist in defense against allegations related to lack of patient instruction.

- Spend some time developing standard patient education handouts for your office.

Consider the top 10 or 20 conditions treated on a regular basis and develop standard patient education materials based on the treatment, care, and preventive care for each condition.

- Allow space in the handout for patient notes, as well as physician or office staff comments or concerns regarding a unique patient situation.
- Document that patient education occurred and patient education material was provided. Include information discussed and that the patient's questions were answered.
- Maintain a copy of education materials given to the patient in his or her record.
- Consider having patients sign the education material and a statement that the physician reviewed the information, the patient had an opportunity to ask questions, and the questions were answered to the patient's satisfaction.
- Review patient education handouts annually to ensure the information is current.

Is this process overkill? In most cases one could certainly consider it aggressive. Yet, it only takes one complaint to open a TMB investigation and the consequences of an investigation can have a serious and long term affect on the physician. Moreover, this patient education process opens lines of communication and helps create a positive physician-patient relationship. Board experience demonstrates that a more open communication style with patients decreases the possibility that a patient or patient's family member may file a complaint.

Finally, the TMB has traditionally required that physicians document patient follow-up instructions in the medical record. Again, it is recommended that a comment be included regarding how the follow-up instructions were provided to the patient (i.e. written, oral or both).

Treatment plans

In certain situations, the Board members expect to see a treatment plan containing more information than what is listed in the four requirements. They actually may request a "treatment plan." This is a written course of action given to the patient with both subjective and objective measures to which the physician and patient agree in order to achieve their stated medical goal. In other words, this is an actual treatment plan that is

provided to the patient and documented in the medical record. It establishes a course of action for the patient and the medical treatment required to meet the standard of care.

Generally, TMB members expect an actual treatment plan for patients who have chronic medical problems. Likewise, patients with highly complex acute problems should have a written treatment plan. Treatment plans should not be regarded as static documents, but as constantly changing based on the condition, the progress of the patient, goal achievement, etc. An evolving document, the treatment plan provides structure for the patient and evidence of success of the treatment or a need to re-evaluate the course of action.

The plan should be developed with input from the patient. If there are other professionals involved in the treatment of the patient, there should be input and consensus from those individuals as well. The parties need to work together to determine if the goals and treatment objectives are being met.

A treatment plan is an absolute requirement when treating patients for issues of chronic pain.¹² The treatment of chronic pain has very specific rules and requirements that are not covered in this article. If you provide treatment to patients for chronic pain, please closely review the TMB rules on that subject and contact people with expertise on this rule, such as TMB staff, attorneys specializing in representing physicians before the TMB, or physicians specializing in pain management.

Documentation that supports billing

Under its rule, the TMB expects to find documentation in the medical record to support billing.¹³ Inappropriate billing not supported by documentation obviously has greater ramifications than action by the TMB. There has been an increase in the number of billing audits and investigations conducted by insurance companies and government agencies. In this author's experience, most people investigated have not engaged in any fraudulent billing. Their care was both appropriate and within the standard of care. However, during investigations it was determined that their documentation did not support the billing. Records with minimal notes may imply that the visit was a simple patient encounter. However, the physician may have spent 30 minutes reviewing medications, vitamins, and herbal supplements with a patient. The key is to document what occurred,

including both the physician's objective determinations, and also the amount of time spent with the patient. Such justifications and documentation may not spare a physician the difficulties of an investigation, but they may prevent prosecution.

The "out" clause

There is an "out" clause for TMB Rule 165.1. The Board acknowledges that the nature and amount of physician work and documentation varies by type of services, place of service and the patient's status. Therefore, these rules are not necessarily one-size fits all.¹⁴ The TMB permits physicians to modify the rules based on "... variable circumstances in providing medical care."¹⁴ However, the results of Board ISCs have proven that these rules should generally be followed under most circumstances. People familiar with this process cannot recall a circumstance where one or more of the rules were waived as a result of unique service or medical specialty provided to a patient.

Changing the record

If a physician determines that it is necessary to change the medical record after the patient encounter notes have been completed, the TMB's rule should be strictly followed. If it is necessary to amend, supplement, change or even correct a medical record, other than at the time you make the original record, it should be done "... by indicating the time and date of the amendment, supplementation, change, or correction, and clearly indicating that there has been an amendment, supplementation, change, or correction."¹⁵ Therefore, when changing the original medical record, be extremely clear that you made the change. In some cases the TMB has even suggested that the physician explain why the change was necessary.

From a practical standpoint, it is best not to alter the original record. If a change is necessary, create a supplemental record clearly indicating the change, the time and date of the supplement, and why it was necessary to create a supplement.

Failure to comply with this rule has almost universally resulted in allegations of a cover-up, fraud, and an attempt to mislead the Board. Such allegations are injurious and are often far worse than the original allegation. Generally, if the TMB believes a physician is attempting to mislead them, they usually

seek to suspend or revoke that individual's license, even if the change was "innocent." The attempt to prove one's innocence is difficult at best. Beyond the TMB, there are other potential civil and even criminal consequences related to changing the record.

Maintaining medical records

Admittedly, medical records can be bulky, unwieldy, and consume a great deal of space. This is especially true when you have not seen a patient for years. Yet, it is the physician's expressed obligation to maintain these records. Failure to do so in the manner prescribed by the TMB is a *per se* violation of the law. It is similar to speeding; if the speed limit is 55 and you are driving 60, you violated the law. Therefore, know the rule mandate and your obligation to maintain patient records in an appropriate manner.

The general rule states that a physician must maintain the patient's medical records for seven years from the date the physician last saw the patient.¹⁶ Thus, in most cases, if you last saw the patient on January 15, 2007, you cannot destroy the records until January 15, 2014.

As with all rules and statutes, there are exceptions. The maintenance of records for minors is generally much longer. For a patient who is younger than 18, medical records must be held for seven years from the last patient encounter, or until the patient turns 21 years, whichever is longer.¹⁷ Therefore, if a physician treats a patient who is 3 years old, the physician must legally hold those records for 18 years. Likewise, if the same patient returns when she is 17 years old and never sees the physician again, the physician must hold all the records for seven years from the date the patient was last seen.

There is no exception for the death of the patient or if the patient moves to another city, state, or country. This rule holds true even if the patient obtains a copy of the medical records and advises that they are moving to another country. The physician is still legally obligated to maintain the record in accordance with the rules.

The other rules are somewhat obvious. For example, the physician cannot destroy medical records if those records are part of a criminal, civil, or administrative suit until the legal action is finalized, even if it is beyond the time limit set by the rule.¹⁸ In these circumstances, check with your attorney or the prosecuting attorney in a criminal matter before destroying

any records.

The rule does not supersede other laws that require the medical records be maintained for a longer period of time.¹⁹ There are various exceptions. When in doubt, contact the TMB or a health care attorney.

Ownership of records

There has been much debate on the "true" ownership of medical records. Physicians and health care entities have the right to possess and transfer medical records to other physicians or groups. But the patients also possess a near universal right to these records.

A physician may transfer ownership of medical records to another physician or group of physicians.²⁰ This is typically done through the sale of a practice. Once this is done in accordance with a specific notice requirement to the patient, then the new physician or group of physicians assumes possession and control of the records and must comply with all the requirements of the TMB.

If a physician is an employee of a group, it is possible that the group "owns" the medical records created by that physician.²¹ If that physician leaves the employment of the group, the records stay with the employer.

In all of the circumstances described above, the physician who created the original record has very specific responsibilities according to the TMB. First, the physician is legally required to give patients notice that he or she is leaving the practice, retiring, closing the practice, etc., and give the patients the opportunity to obtain copies of their records, or make arrangements to have them transferred to another physician.²² It is important to make it clear that if the physician is an employee of a practice, that physician is responsible for the notice, not the employer.²³

Additionally, the physician is also required to notify the TMB that they are transferring ownership of the records or leaving the group's employment and will no longer be available to those patients.²⁴

The notice to patients must be specific. It must inform patients that the physician intends to retire, terminate employment or otherwise leave the medical practice, and will no longer be available to patients.²⁵ The notice must also include information about how the patient may obtain a copy of his or her medical records.

No less than 30 days before the date of termination, sale, or relocation of the practice, the physician must provide a copy of the notice to the TMB.²⁶ The physician must pro-

vide three separate methods of notification to patients. The first method is to mail a letter to all patients seen within the past two years, to their last known mailing address.²⁷ The letter must advise them of the intent to leave and their rights to their medical record. The letter must also explain how they may obtain a copy of their medical record in the future.

The second method is to publish the notice in the newspaper of greatest general circulation in each county in which the physician practices, and also in a local newspaper that serves the immediate practice area.²⁸ Again, the notice must advise the reader of the physician's intent to leave and the right of the patient to obtain their records. Additionally, it should explain to patients how to access their records in the future. The notice needs to be large enough so that a reasonable person can see it. It should not be hidden away in the classified section. The TMB does not state how often it should be publicized; however, it is advisable to publish the notice twice over the course of one month.

The third method is to place a written notice in the office.²⁹ The TMB requires that the written notice be posted in a conspicuous location or on the facade of the physician's office.³⁰ Again, the notice must state the physician's intent to leave and the right of the patients to obtain the records. Importantly, the sign must be in place no less than 30 days before the change in the practice status.³⁰

It is important to emphasize that this rule applies even if the physician leaving is a member of a group. It is a violation of TMB rules for any other licensed physician remaining in the practice to prevent the departing physician from posting notice in the office.³¹ The TMB has the ability to prosecute in these situations. Moreover, the remaining physician or physicians cannot withhold information from the departing physician necessary for mailing notification to that individual's patients.³² If the departing physician requests the addresses of his patients for the past two years, that information cannot be withheld. Very likely, it is legally permissible to restrict that information. For example, the office may print the letters, but not physically provide the list of patients to the departing physician, especially if it is presumed to be a trade secret by the office. The remaining physician or physicians should use caution in this regard and permit the departing physician to provide notice and not interfere with that legal obligation.

Custodian of records

In very rare circumstances, medical records may be designated by the TMB as abandoned. According to the Board, medical records are abandoned when they are without custodial care for a minimum of two weeks, without alternative arrangements made by the physician, the physician's legal guardian, or by the executor of the physician's estate.³³ When it comes to estate planning, it is important to be very clear on a chain of custody for possession and control of medical and billing records.

If the TMB determines that records are abandoned, the Board may appoint a temporary or permanent custodian for medical records. A person or entity must apply to the TMB to become the record custodian.³⁴ This is typically accomplished with a bidding process through state contract services.³⁵ Once the TMB makes such an appointment, the record custodian must take custody of the records and maintain their confidentiality.³⁶ The record custodian must follow and adhere to all TMB rules as well as other state and federal rules relating to the medical and billing records.

The record custodian shall provide the records to patients or their authorized representatives pursuant to TMB rules.³⁷ They may charge a reasonable fee for the records (see below). The record custodian shall retain care of the records for no less than 90 days and shall publish appropriate notice of pending destruction of the records for no less than 30 days before destruction of the records.³⁸ TMB rules do not define appropriate notice. It may be a newspaper notice similar to that required of a physician when providing notice of leaving practice. After the minimum of 90 days, and once notice has been properly given, the records should be destroyed by a method that ensures continued confidentiality.³⁹

Releasing medical records

Generally speaking, upon written consent for the release of medical records by a patient or his or her guardian (either a legal guardian or a parent), a physician must release a copy of the medical records, billing records, or a summary of the records, including those records received from other physicians or health care providers.⁴⁰ A subpoena is not required if the physician receives a written release from the patient or the patient's guardian.⁴¹ Please note that each is a request unto itself, meaning if a patient only requests

the medical records, the physician is not obligated to release the billing records.⁴² By law, the physician has 15 business days to copy and submit the records as requested or to advise the patient of the cost to obtain the records.⁴³ However, if you charge for the records, you have 15 days from receipt of payment.⁴⁴ It is strongly suggested that records be released using a method to verify they were received and by whom (i.e. certified mail return receipt requested). If the patient personally picks up the records, the patient should sign an acknowledgement stating he or she received the records. Maintain a copy of either the certified mail receipt or acknowledgement in the medical record. This is an important defensive tool for physicians.

The only exception to releasing records is when the physician, in his or her professional opinion, reasonably believes that access to the information would be harmful to the physical, mental, or emotional health of the patient.⁴⁵ If the physician does reasonably hold such a belief and chooses to deny the request in whole, or in part, the physician must provide a written rationale for the decision to the requestor.⁴⁶ This must be signed and dated by the physician. This written statement must be placed in either the medical or billing record, depending on which record was denied.⁴⁷ This also must be provided within 15 days.⁴⁸

In addition to the rationale for the denial, the physician is also required to provide information to the requestor regarding the process for the patient to file a complaint with the Department of Health and Human Services and the TMB.⁴⁸ If the patient continues to request the medical record after a denial, the physician is still under a legal obligation to continue to explain the rationale for the denial each time the record is requested. It is important to note that mental health records have some additional legal requirements and these should be reviewed.⁴⁹ Failure to adhere to these rules has resulted in public disciplinary action by the TMB. These disciplinary actions usually range from a \$500 to \$1000 fine, continuing education courses in record-keeping, and even public reprimands, which are reportable to the National Practitioner Data Bank. Repeat violators may face far harsher treatment.

It is equally important to note that medical and billing records properly requested cannot be withheld from the patient or other authorized individual because the patient owes the physician money.⁵⁰ The TMB has

been strongly enforcing this provision of the rules.

The physician may charge a fee for copying and shipping records. The physician is entitled to receive a "reasonable fee" to recover the cost of producing the record. It is important to note that the physician is not obliged to charge a fee or charge a reduced fee. Currently, the TMB deems a reasonable fee to be no more than \$25 for the first 20 pages and 50 cents per page thereafter.⁵¹ Therefore, if someone requests their medical records and it is 3 pages, the physician can charge \$25 for those records. If there are 21 pages, the physician may charge \$25.50 for the records.

If the records require an affidavit certifying the information is true and correct, the physician may charge an additional fee of \$15 for executing the affidavit.⁵¹ When calculating fees, the TMB considers billing records and medical records separate documents for the purposes of charging a fee.⁵¹ Therefore, it is permissible to charge \$25 for the first 20 pages of medical records and \$25 for the first 20 pages of billing records.

Additionally, the physician is permitted to charge for mailing or shipping⁵² the record and the cost of preparing a summary of the records when appropriate.⁵³ The physician cannot charge any costs associated with searching for the records and retrieving the records. This is of particular importance to physicians who use document storage services for archiving medical records. If a patient requests records, you need to ensure that your service will be able to locate and produce the record for copying within 15 days of receipt of the request for the records. Failure to comply will result in prosecution by the TMB.

If a physician receives a proper request for records, the physician may retain the requested information until payment of the reasonable fee is received. If payment is not made within 10 calendar days after receiving a request, the physician shall notify the requesting party in writing of the need for payment and may withhold the information until payment of a reasonable fee is received. A copy of the letter regarding the need for payment shall be made part of the patient's medical and/or billing record as appropriate.⁵⁴

All such letters are important if physicians need to defend claims that they failed to comply with a request for release of records. The physician should follow the stated timeline and provide the appropriate information to the patient to use this defense.

There are exceptions to charging fees. If another physician requests the record for the purposes of an emergency or an acute medical condition, the physician providing the copies cannot charge a fee.⁵⁵ There are various state and federal laws that prohibit charging a fee for records. Hopefully, the requestor will know and inform the physician of such a circumstance. The most common exception for Texas physicians is when a patient needs the records for the purposes of demonstrating or applying for benefits and assistance claims relating to the patient's disability.⁵⁶

These rules are viewed by some to be in conflict with federal law, particularly the Health Insurance Portability and Accountability Act (HIPAA) 45 C.F.R. Parts 160-164. If you have questions, it is recommended that you contact an attorney with experience in this area, the TMB, or review the TMB rules.

Diagnostic imaging studies in the possession and control of a physician are treated similarly to a medical record. Patients may submit a written release, similar to that of a medical record release, for x-ray film or other static diagnostic imaging studies. The physician can comply with the rule by either providing the patient with a copy of the film or image, or providing the original.⁵⁷ Should the physician, for whatever reason, choose to provide the patient or the patient's representative with the original, the physician must receive a signed and dated receipt from the recipient acknowledging receipt of and responsibility for the original studies.⁵⁸

As with medical or billing records, the physician can determine that access to such records would be harmful to the patient, and therefore deny access.⁵⁹ The physician must provide a written justification for such a decision and the notification of the process for filing a complaint with the federal Department of Health and Human Services and the TMB.⁶⁰ A copy of the statement denying the request should be placed in the patient's medical records.

Similar to medical and billing records, the physician can charge a reasonable fee for film and images. The fee can be no more than \$8 per copy.⁶¹ Additionally, the physician may charge a reasonable fee for actual costs of mailing, shipping, or delivery.⁶¹ Again, there should be some form of verification that the patient or the patient's representative received the films and images. Similar to medical and billing records, the physician is permitted to withhold the film until receipt of payment for the cost of the copies.⁶² The physician is obli-

gated to request payment within 10 calendar days from receiving a request.⁶² The request cannot be withheld due to balance owed for medical services.⁶³ If there are emergency circumstances, the physician cannot withhold the images for payment of the reasonable fee.⁶⁴ Further, the physician must abide by other more specific statutes and rules that require fees be reduced or waived.⁶⁵

Conclusion

The rules for medical records are complex and can cause confusion. Physicians must create and maintain appropriate medical records and ensure that employees understand the importance of being responsive to medical record requests. Carelessness and ignorance of TMB rules have resulted in TMB sanctions for many physicians. In either case, the Board has little patience for poor documentation or abuse of the patients' rights to gain access to their records.

Taking time with patients and their records will benefit the physician by providing better patient services and avoiding TMB complaints.

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Editor's note: TMLT offers an online CME course, "TMB Investigations" that explains the role, purpose, and basic formation of the TMB, and details how an investigation is started and conducted. This course is available at www.tmlt.org.

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EXPIRED CME**CME test questions**

Instructions: Using black ink, read each question, select the answer, and then clearly mark your selection. Please fax the completed test and evaluation forms to the Risk Management Department, attention Rebecca Henson 512-425-5996. You can also mail the test and evaluation forms to the TMLT Risk Management Department, attention Rebecca Henson, 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.

1. TMB rules require that records from other health care professionals involved in the care of a patient shall be maintained as part of the medical record.

True

False

2. The records of deceased patients may be destroyed upon notification of death.

True

False

3. By law, a physician has how many business days to copy and submit properly requested records.

10 days

30 days

15 days

None of the above

4. Under no circumstances can a physician refuse a patient's request for release of records.

True

False

5. Physicians may not withhold properly requested records if the patient has an unpaid account.

True

False

Statement of completion

I attest to having spent _____ hours in this CME activity.

Physician signature _____ Date _____

CME evaluation form

Please complete the following regarding the article, "Dissolute Documentation."

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

Through the labyrinth



the TMB investigation and litigation process

By Jill Wiggins

Texas physicians read the *Medical Board Bulletin*, the newsletter of the Texas Medical Board, (TMB) to find out who has been disciplined. Each of those actions in the newsletter is the result of a complaint being filed, an investigation being completed, and the Board determining there was a violation of the Medical Practice Act. Filing a complaint with the TMB triggers a process far more complex than the average physician imagines.

In 2003, the Texas Legislature mandated changes to the Medical Practice Act requiring the TMB to complete the complaint investigation process within 180 days. TMB staff has developed processes to meet that mandate for complaints that are determined to be a possible violation of the Medical Practice Act. This article will follow a complaint as it moves through this labyrinth.

The first step of the process — a complaint analyst reviews the complaint. The analyst must determine if the complaint falls under the Board's jurisdiction. It must be against a physician, physician assistant, acupuncturist, non-certified radiologic technician or surgical assistant. If the complaint involves someone the TMB does not license, such as a dentist, the complaint is sent to the appropriate agency.

Once it is determined that the case falls under TMB's jurisdiction, staff will search the National Practitioner Data Bank and other entities to determine if the physician has any disciplinary history. A staff

member then contacts the complainant to clarify the facts of the complaint. Staff also sends a letter to the physician asking for a response to the complaint. If the physician presents evidence that there is no violation, the case is counted as "jurisdictional — not filed." For example, the complaint may be that the physician failed to take X-rays, and if the physician submits those X-rays, there is no violation found. If the staff member finds that the allegations — if they prove to be true — would violate the Medical Practice Act, the case is filed as a complaint and assigned to an investigator.

About 60% of TMB investigations are based on an alleged violation of the standard of care. The remaining investigations involve boundary issues, impairment, inadequate medical records and some lesser violations that are assessed as "minimal statutory violations."

Every standard of care case opened by the Board must be reviewed by at least two physician consultants in the same or similar specialty as the respondent. The TMB has a large roster of consultants available, and after the medical records are subpoenaed, they are provided to the lead panelist and a second panelist. If both physicians agree there is no violation, the case is recommended to the Board for dismissal. If they both agree that there is a violation

of the standard of care, the case goes forward. If they disagree in either direction, the case goes to a third panelist. If two of the three say there is no violation, the case is recommended for dismissal. If two agree there is a violation, the lead panelist prepares a report and the case goes back to an investigator, who prepares a final summary.

Once the case has made it this far, it is reviewed by the Quality Assurance Committee. The committee comprises the enforcement director, the litigation manager, and the executive director, who may recommend the case for dismissal or move it forward into litigation.

Once a case is turned over to the Litigation Department, the TMB has another 180 days to bring it to a hearing. The case is assigned to a Board attorney and another complex process begins.

First, the attorney reviews the case for sufficiency. If it is deemed sufficient, the attorney proceeds. If the attorney finds the case to be insufficient, it is reviewed by the legal management team. The case is then either returned to investigations or is sent to the attorney for guidance on how to proceed.

Next, a legal assistant prepares case materials and an informal settlement conference (ISC) is scheduled. The respondent is notified at least 60 days before the ISC. The

attorney finalizes the allegations for the Board disciplinary panel that will hear the ISC proceeding. At least 30 days before the hearing, the ISC packet is distributed to the disciplinary panel, the respondent, and the hearings counsel.

Finally, within a year after the complaint was opened, a disciplinary panel hears the case in an ISC. The disciplinary panels are drawn from the Board and from disciplinary review committees representing all regions of Texas. By law, each disciplinary panel must be made up of at least one physician and at least one public member.

The respondent usually attends the ISC, and is encouraged to do so with legal counsel. The Board's attorney presents the case, and the respondent and counsel have an opportunity to respond. Complainants and other witnesses may also appear.

Once each side has presented, the disciplinary panel deliberates and makes a recommendation for Board action. They may recommend that the case be dismissed, or they may recommend an agreed order with various terms and conditions. For exam-

ple, if they see a particular area of skill that the physician is lacking, they may recommend the physician be allowed to continue practicing, but prohibit that procedure. The panel could also recommend the physician complete additional training or CME or require the physician to employ a chart monitor or practice monitor. An administrative penalty (fine) may also be assessed.

If the disciplinary panel recommends dismissal, a Board committee reviews the case and recommends final disposition. This committee usually agrees with the panel's recommendations for dismissal, but occasionally a case is returned to staff for further investigation.

If the disciplinary panel finds a violation occurred, but the respondent does not agree to the order, the case goes to the State Office of Administrative Hearings (SOAH) for a contested case hearing.

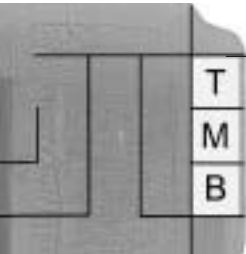
If the respondent accepts the agreed order, it still must be approved by the full Board, which usually happens at the next Board meeting. The Board approves most agreed orders, but it sometimes disagrees

with the panel's recommendation and does not approve an order, asking that it be modified. If the physician does not agree to the modified order, the case goes to SOAH.

Once the physician has signed an agreed order, TMB compliance officers follow up to make sure the physician complies with the terms of the order. Orders can include public reprimands with no further penalty; fines; training requirements; license restrictions for one year, two years or longer; suspension of the license (sometimes a suspension is probated and the physician is allowed to practice). The Board cannot revoke a license unless the physician agrees to it or the case goes through SOAH. Many orders contain language allowing the physician to come back to the Board and ask for early termination or modification of an order if the physician shows full compliance.

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Other common violations



In addition to standard of care violations, which account for about 60% of TMB disciplinary actions, there are many other ways a physician can get into trouble with the Board. Some of the most common non-standard of care violations are listed below. Board rules that are cited can be found at www.tmb.state.tx.us/rules/rules/bdrules.php.

Non-therapeutic prescribing — the Board has taken an increasing number of actions against physicians who prescribe without a valid reason; who prescribe the same “pain cocktail” to every patient, frequently on a cash basis; and who prescribe to known abusers.

Prescribing to self, family, friends or employees without keeping medical records. This violation can trip up well-meaning physicians. According to TMB rules, such prescribing is a violation if it's done “without taking an adequate history, performing a proper physical examination, and creating and maintaining adequate records.” Most TMB actions related to this violation involve prescribing controlled substances. It is always wise to create a patient record for anyone to whom a physician prescribes.

Impairment due to alcohol or drugs — physicians practicing while under the influence of alcohol or drugs are a danger to themselves, patients, and the public. The TMB has a rigorous drug testing program for physicians under orders for impairment. A self-reported problem with drugs or alcohol, if there has been no other complaint and no patient harm, may allow for a nonpublic, nondisciplinary order.

Boundary violations are formally cited as “inappropriate conduct involving physician-patient relationship.” Sometimes sexual

or romantic, sometimes financial, such personal relationships can harm patients and ruin a physician's reputation. Avoid becoming emotionally or financially involved with patients outside the office.

Inadequate medical records make it difficult to determine whether a physician is practicing within the standard of care. When a patient files a complaint and the records are inadequate to confirm why the physician did what he or she did, the Board may take action on the inadequacy of the records.

The Board has the authority to enter agreed orders without an informal settlement conference for certain violations. These are referred to as “minimal statutory violations” and can include:

Failure to provide medical records in a timely fashion — the TMB rule requires a physician to provide properly requested records within 15 business days.

Failure to store or discard records in a manner that preserves confidentiality. The full medical records rule is Chapter 165.

Failure to obtain required CME. Board rules require at least 24 hours of CME, with at least 12 hours being category I, and at least one hour in ethics or professional responsibility. Additional requirements can be found in Chapter 166, section 166.2.

Inappropriate advertising includes advertising that is misleading or contains testimonials. Touting nonexistent board certification, or certification with a non-approved board, is also a violation of Chapter 164 of the Board rules.

Failure to sign a death certificate. Section 193.005(c) of the Texas Health and Safety Code requires that a physician sign a death certificate within 10 days of receipt.

closed claim studies

Failure to timely evaluate patient

by Barbara Rose and Laura Brockway

The following closed claim studies are based on actual malpractice claims from Texas Medical Liability Trust. These cases illustrate 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 physicians' defensibility. The ultimate goal in presenting these cases is to help physicians practice safe medicine. An attempt has been made to make the material more difficult to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.

Presentation

A 25-year-old man came to the emergency department on a Thursday with complaints of left upper quadrant abdominal pain. He was evaluated by an emergency medicine physician. Imaging studies and lab results were unremarkable. The patient was given a "GI cocktail" and pain medications that improved his symptoms. The final diagnosis was "acute abdominal pain, rule out peptic ulcer disease versus gastritis." The physician documented his plan: "He is to follow up with the gastroenterologist tomorrow or Monday and return immediately for any change or worsening." The patient was referred to a gastroenterologist and discharged.

The patient returned to the ED on Saturday, two days after his initial visit, with continued abdominal pain. He was seen by another emergency medicine physician whose examination revealed diffuse abdominal tenderness. Lab studies were unremarkable. An abdominal CT with contrast was interpreted as non-specific, suggesting the possibility of a mild ileus, "but certainly no obstructive effect is seen." The differential diagnosis included inflammatory bowel disease, enteritis, early appendicitis, and early bowel obstruction. The physician documented that he did not feel the patient had a surgical abdomen, and noted he had an appointment with a gastroenterologist on Thursday. The patient was discharged with instructions to return if he experienced

increased pain, fever, vomiting, or blood in the stool.

When the patient returned to the ED on Sunday, the ED physician obtained a surgical consult. The surgeon did not believe the patient had a surgical abdomen and recommended referral to a gastroenterologist. The ED physician called a gastroenterologist who agreed to admit the patient.

Physician action

The gastroenterologist saw the patient at 5 p.m. He requested a surgical consult and ordered repeat scans of the abdomen and pelvis. He requested the scans "tonight" and that he be contacted by telephone with the results. The coding sheet for the imaging studies indicate the order was received "stat" at 5:05 p.m.

That evening, the patient developed fever and tachycardia. The gastroenterologist was contacted, and he ordered blood culture testing and antibiotics. He again instructed "call tonight for problems and results of abdominal CT." The patient was not taken to radiology until approximately 11:30 p.m. and returned to the room at 1:30 a.m. The records reflect that the gastroenterologist was called by the nursing staff two more times overnight, but was not advised of the results of the CT scan. The gastroenterologist did authorize the patient to receive clear liquids by mouth. Documentation received during the investigation of this claim suggested that the radiology tech who obtained the CT scan called an administrative person at the radiology group to advise that he would be sending over images by teleradiology for a stat interpretation. The tech did not speak directly with the on-call radiologist.

At 6:15 a.m., a general surgeon saw the patient. He reviewed the original CT films and diagnosed a small bowel obstruction. He took the patient to surgery for an urgent laparotomy. Of note, the formal radiology report with the results of the abdominal CT were called in to the gastroenterologist at

6:10 p.m. that evening. There was an apparent breakdown in communication between the radiology department and the radiologist responsible for interpreting the CT scan.

The patient was taken to surgery, and anesthesia induction began at approximately 7:50 a.m. During induction, the patient aspirated a large amount of stomach/bowel contents. During surgery, the surgeon evacuated approximately 3 liters of feculent matter from the patient's stomach and small bowel through a nasogastric (NG) tube. The surgeon then located a bowel obstruction at the distal terminal ileum. He felt that the obstruction was caused by a congenital fibrous band of tissue across the bowel. The non-viable segment of bowel was resected and the bowel closed with an end-to-end anastomosis. The surgery was completed and the patient was transferred to the ICU.

The patient remained intubated after surgery. In the following days he developed acute respiratory distress syndrome and aspiration pneumonitis. The patient's condition deteriorated to multi-organ failure. He suffered a cardiac arrest and died nine days after the surgery.

Allegations

Lawsuits were filed alleging:

- failure to admit the patient to the hospital after his second visit to the ED (EM physician);
- failure to timely obtain surgical consultation and failure to timely follow up on the results of the stat CT scan (gastroenterologist);
- failure to timely interpret and report the results of the stat CT scan (radiology group);
- failure to timely evaluate the patient; failure to order NG tube drainage of the patient's stomach contents before surgery; and failure to assure proper anesthesia procedures during surgery (general surgeon); and
- failure to take appropriate measures to prevent regurgitation during induction of anesthesia (anesthesiologist and anesthesiology group).

continued on page 20

Delay in reporting test results to patient

by Barbara Rose and Laura Brockway

Presentation

A 42-year-old man came to the emergency department (ED) with complaints of chest pain. A full work-up in the ED did not reveal any cardiac problems. The patient was told to follow up with his primary care physician. The patient's internal medicine physician referred him to a cardiologist because the patient had a significant history of cardiac disease (his father and uncle both died from myocardial infarctions).

Physician action

The patient went to the cardiologist a few days after the ED visit. A stress test and myocardial perfusion test were ordered. The stress test was performed that day and the myocardial perfusion test was performed two days later. The consult, stress test report, and perfusion report involved 3 different specialists in this cardiology group practice.

The patient's wife called for the test results on Tuesday, three days later. She was advised that they were unavailable and told to call again Friday morning. Calling again on Friday, the patient's wife told the receptionist that her husband had continued chest complaints. She was told a nurse would call her back. Hearing nothing, the patient's wife called again at noon and was told the results were unavailable. She was told a nurse would call her that afternoon.

The patient came home that afternoon at 5 p.m. with increased chest pain and he reported feeling ill. The patient's wife called the cardiologist's office and reached the answering service. At 5:08 p.m., a nurse from the practice called. The nurse told the patient's wife that she would try to determine the results of the studies, but said in general if they were "positive," the cardiologist would have had the patient come in for further evaluation. The nurse advised that the patient should continue to take his nitroglycerin if he was having chest pains. If he had no relief, he should go immediately to the ED. The patient's wife disputes that the nurse told them to go to the ED if the chest pain continued.

On Saturday morning, the patient went to his son's sporting event, but felt ill and returned home. He contacted his internal medicine physician. He told her the test results were not yet available, and that he was continuing to have back and chest pain. The patient also told his physician that the nurse told him that if the results were positive, he would already have been called. After hearing the patient's com-

plaints, the internal medicine physician felt he was suffering from GERD or possible gallbladder or appendix irritation. She called in a prescription for stomach medication and said she would personally follow up on the tests Monday morning.

That afternoon, the patient's son found him at home in full cardiac arrest. EMS was called and paramedics attempted to resuscitate the patient, but he died on the way to the hospital. An autopsy found that the patient had a 100% occlusion in one vessel, 80% stenosis in the LAD vessel, and 80% stenosis in the PDA vessel. The cause of death was listed as arteriosclerotic cardiovascular disease; hypertension.

The results of the tests performed by the cardiologist were not transcribed until two days after the patient's death (11 days after the stress test and 9 days after the myocardial perfusion test). Both tests were read as "normal."

Allegations

A lawsuit was filed against the cardiologist and his practice group. The plaintiffs alleged negligence in evaluating the stress and myocardial perfusion tests; delay in reporting test results to the patient; and failure to immediately refer the patient to the ED. The plaintiffs were also critical of the practice for failing to have procedures that would have assured quicker reporting of test results. The allegations also included wrongful death.

Legal implications

Three board certified cardiologists reviewed this case for the defense. They believed the stress test was read appropriately, especially since the patient completed the entire treadmill test without chest pain or significant EKG changes. A nuclear imaging expert also reviewed the images from the myocardial perfusion test. Initially, he read them as "normal." However, retrospectively, there was some evidence of decreased perfusion in the area of the heart where the occlusions were found on autopsy. The expert said he would have to testify that retrospectively, the study was "abnormal."

All the experts who reviewed this case believed there was some delay in interpreting the nuclear imaging portion of the stress test. Additionally, there was some criticism of the nurse's inappropriate advice to the patient regarding test results as she informed his spouse, if they were positive, the patient would have been contacted.

Finally, all the experts agreed that if the patient's condition had been diagnosed and treated appropriately he would have survived and led a fairly normal life. His life expectancy probably would have been reduced by 10 years and his work life expectancy would have been reduced by 2 to 3 years.

Disposition

This case was settled on behalf of the cardiologist and the professional association.

Risk management considerations

Providing quality patient care with an emphasis on patient safety and a decrease in medical errors has long been a focus among health care providers. This commitment transcends all areas of health care (inpatient, outpatient, all physician practice venues). All physicians need to develop and implement strict protocols for timely dictation and transcription of findings, patient follow up, and recommendations pursuant to their patient encounters. With such a significant family history, would a cardiologist consider this patient at high risk? Does the index of concern and suspicion increase? Do pending tests for a patient like this justify timely interpretation, transcription, and further action?

Another issue of note in this claim involved the difference in recall between the nurse in the defendant's practice and the patient's spouse. Clear guidelines regarding staff responsibilities when talking to patients or family members in person or by phone/e-mail are relevant for all practices. Each of these encounters needs to be documented in the medical record as part of the chronological diary reflecting patient care. Thus one can avoid a debate regarding whose memory is correct.

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continued from page 18

Legal implications

Three consultants reviewing this case for the defense were critical of the care provided by the general surgeon and the gastroenterologist. Specifically, the defendants should have ordered placement of an NG tube to relieve stomach content pressure when the diagnosis of small bowel obstruction was made. The consultants also voiced criticism of the anesthesiologist for failing to protect against aspiration by performing rapid sequence induction with cricoid pressure.

The plaintiffs were able to obtain expert support for their theories of liability. At deposition, the plaintiff's experts stated that if it had not been for the aspiration event, the patient would have survived the surgery without complication. It was further claimed that the failure to order an NG tube was a proximate cause of the aspiration event. These allegations were directed only toward the general surgeon and the anesthesiolo-

gist. The plaintiffs did not assert that earlier diagnosis and surgery would have prevented the aspiration. This lack of testimony regarding proximate cause weakened the case against the EM physician, the radiology group, and the gastroenterologist.

Disposition

The claim against the emergency medicine physician was dropped early in the development of the case. The plaintiffs also agreed to dismiss the cases against the radiology association and the gastroenterologist.

The cases against the general surgeon, the anesthesiologist, and the hospital were settled.

Risk management considerations

To comment on the outcome of a closed claim with the benefit of hindsight offers the opportunity to evaluate what occurred and to determine where changes might be needed to avoid similar scenarios in the future. With multiple physicians of differ-

ent specialties and multiple hospital departments and their staffs involved, breaches in timely communication and patient care may and do occur as reflected in this case. Physicians and inpatient staff members must be vigilant as a patient's condition deteriorates and timely decisions become urgent.

Although not described as directly relating to this patient's death, two aspects of his care should be reviewed. What are the hospital's protocols regarding a stat order? Is a six-hour delay acceptable and within the guidelines? What checks are in place to verify that a stat imaging study has been forwarded to the radiologist on duty and interpreted right away?

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