

PHYSICIAN *Risk Management*



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Time-stamped EMR entries turn cases from defensible to candidates for settlement

It's a reason for jury to question physician's integrity

During recent malpractice litigation, it was revealed that the defendant nurse had "forward charted" a number of standard items about the patient's condition throughout the shift.

"Many of these items would have been expected to be true, such as 'patient sleeping comfortably,' but unfortunately turned out not to be true at all," says **Scott Martin, JD**, a partner with Husch Blackwell in Kansas City, MO.

Although the patient was charted to have been "sleeping comfortably" at 03:00, the fact was that there was a full code taking place at 03:00. "Based in part on the time-stamping of the early entry as compared with the code documentation, plaintiff's attorney was easily able to identify the improper charting and then skewer the nurse with it," says Martin.

Time-stamped electronic medical record (EMR) entries complicated the defense of a malpractice case involving a 58-year-old patient with a brain tumor who became quadriplegic secondary to an intraoperative complication. The plaintiff argued that hypotensive episodes during the case led to cord ischemia.

When the plaintiff in this case analyzed the EMR audit trail, it was discovered that the anesthesiologist documented that he had been present at the end of the case, but he did so hours before the case ended.

Everything the anesthesiologist did was then subject to question, says **Jonathan M. Fanaroff, MD, JD**, associate professor of pediatrics at

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PRM focuses on EMR charting

This month's issue of *Physician Risk Management* is a special issue on electronic medical record (EMR) charting and malpractice litigation. Inside, we interview leading legal expert, patient safety, and risk management experts to report on how EMRs are being used to prevent malpractice claims alleging failure to follow up on abnormal test results, how "metadata" is complicating the defense of some malpractice lawsuits, and how physician practices can fine-tune EMRs to decrease legal risks. In the supplement, *Legal Review and Commentary*, our legal authors analyze a case and explain why defending on the basis of the medical record alone might be a difficult, if not impossible, proposition.

FINANCIAL DISCLOSURE: Physician Editor, **Jonahan Fanaroff, MD, JD**, discloses that he is on the advisory board for AbbVie and Discovery Laboratories. Author **Stacey Kusterbeck**, and Executive Editor **Joy Dickinson**, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

Case Western Reserve University School of Medicine and co-director of the Neonatal Intensive Care Unit at Rainbow Babies & Children's Hospital, both in Cleveland, OH. "He very well may have been there the whole time, but any jury would question his integrity," Fanaroff says. The case went to trial, but was settled during the trial.

Critical piece of evidence

Time stamps complicate the defense if they provide a reason to question the physician's honesty.

"Plaintiff lawyers may try to insinuate wrongdoing based on time stamps, such as asking why a physician looked at the record or printed out certain documents," says Fanaroff.

Any malpractice case involves the development of a narrative, often competing narratives, regarding what happened and when, says **David S. Waxman, JD**, an attorney with Arnstein & Lehr in Chicago.

"The time stamp is obviously a critical piece of evidence helping to

determine the 'when,'" says Waxman. In some cases, however, the time stamp doesn't reflect when certain events occurred. It only reflects when they were charted.

"Depending on how the events and care are memorialized, the time stamp created when the physician's note is finally inputted can warp the narrative and allow for the creation of a story, which may be plausible but untrue," says Waxman.

There is a constant tradeoff between efficiency and completeness of charting, he acknowledges. "But when it comes to timing of important

events in a patient's care, whether it be a change in the patient's condition, receipt of test results, or issuing new orders, making the effort to note when those events occurred is well worth the minimal investment in time required," says Waxman.

Defense must explain EMRs

Time-stamped EMR entries can be confusing to a jury, because the historic expectation is that the time noted represents the time of the event, not the time of the charting.

"Most adults have seen some type

Executive Summary

Time-stamped electronic medical record (EMR) entries can complicate the defense of a malpractice claim if they provide a reason to question the physician's credibility.

- ◆ The defense must explain that entries don't necessarily indicate when something was done.
- ◆ Time stamps can make a case more defensible if they support the provider's version of events.
- ◆ In some cases, time stamps have shown that entries were "forward charted" before an event occurred.

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of paper chart based on the time-noted process, but relatively few are familiar with how computer charting may be different,” says Martin.

The specific sequence and timing of events is often critical in malpractice cases. “A handful of minutes may have literal life and death consequences, especially in a code situation,” says Martin. “Even if a few minutes may not matter, a few hours often will.”

End-of-shift notes are generally time-stamped after a shift has ended, but they refer to events that occurred throughout the shift. “If there are not individual times referenced within the note, it will be difficult to place events in the proper sequence,” says Martin. Once a plaintiff’s attorney identifies

inconsistent items in a chart, she will often urge the fact finder to mistrust the entire chart. “Then the defense is forced to explain the medical care and the chart,” says Martin.

Give reason for late entry

Whenever an EMR entry is made after the fact, the physician should document the reason for the late entry, advises Fanaroff.

“Medical and nursing staff need to identify the actual time of events and not rely on the time-stamp,” says Martin. “This sounds basic but is not universally done.”

Clinicians should absolutely not document the outcome of an

event or procedure in advance, says Fanaroff. “It is difficult to find a legitimate reason to document something before it occurred,” he says. “It may be that it was done in the paper era just to be sure that the charting was complete.”

Changes or corrections might not be visible on the EMR screen. “But the paper printouts of charts I have reviewed identify original and revised versions of a record,” says Martin. The author and timing of any changes are also identifiable.

“I have not seen an after-the-fact effort to falsify an electronic chart,” says Martin. “But the only time I had heard of that in a paper chart, the whole case became indefensible.” ♦

Prevent claims alleging failure to follow up on abnormal test results

Results management’ systems alert providers

The largest and fastest growing group of malpractice claims in the United States involves missed and delayed diagnoses, specifically of lung, prostate, and colorectal cancer, as well as myocardial infarction, says **Saul Weingart**, MD, MPP, PhD, chief medical officer at Tufts Medical Center in Boston.

Failure to follow up on abnormal test results contribute significantly to these missed diagnoses, especially relevant laboratory tests, imaging, and EKGs, he says.

“The abnormal test follow up process is more complicated than one might imagine,” says Weingart. He says that each of these steps is subject to a “low but real” risk of failure: test selection, test completion, result receipt, result interpretation, and result notification.

Weingart says EMRs can help to prevent missed diagnoses if they incorporate “results management” systems. These track outstanding

clinician orders for diagnostic tests. They notify the provider if the test is incomplete within a specified time period, if the test has been resulted, and if abnormal findings have been posted. “Strong systems allow for forwarding of results to covering clinicians, and for auditing or oversight of results that have not been acknowledged within a specified timeframe,” says Weingart.

Some systems generate templated results letters to streamline patient notification. “These systems help to backstop the ordering clinician by creating a fail-safe mechanism to ensure and record that test results have been acknowledged and acted upon,” says Weingart.

More colonoscopies obtained

When **Mark Aronson**, MD, acting chief of the Division of General Medicine and Primary Care at Beth Israel Deaconess Medical Center in

Boston, sends patients for a colonoscopy, “often, I see them the next year, and they tell me they couldn’t find the time to do it.”

A referring tracking system was developed for the organization’s EMR, funded by the hospital’s malpractice insurer. The patient is sent a letter and two phone calls, if patients don’t make an appointment in a certain timeframe. “As a result, we have screened hundreds of patients,” says Aronson. “We have picked up several important findings, such as colon cancer, in a number of patients.” (See related story, p. 3, on patients’ failure to obtain recommended testing.) The system sends test results to the ordering provider and allows providers to compare these to previous results. “It gives them the option of calling the patient and discussing the results at that very moment,” says Aronson.

The system is especially helpful when followup is recommended for a future point in time, such as a

radiologist's recommendation that a lung nodule noted on a patient's X-ray be followed in six months. "That turns out to be very hard for doctors to do by themselves," says Aronson. The EMR flags the provider to contact the patient in six months to remind them of the need for the followup test.

The system notifies the patient's primary care physician of any unrelated, unusual finding. A stroke patient admitted from the emergency department might have an X-ray

EXECUTIVE SUMMARY

Electronic medical records (EMRs) can potentially help to prevent missed diagnoses with "results management" systems that track outstanding clinician orders for diagnostic tests.

- ◆ Providers are notified if the test is incomplete within a specified time period, if the test has been resulted, and if abnormal findings have been posted.
- ◆ Some tracking systems give results on all types of tests to the ordering provider and allows providers to compare these results to previous results.
- ◆ Patients are contacted by phone and letter if they fail to obtain a recommended test.

showing a lung module, for example. "We are working with radiology to

develop a tracking system for incidental findings," reports Aronson. ♦

Use EMRs to document follow up with patients

It could be important evidence in litigation

To avoid malpractice claims resulting from a patient's failure to follow up with recommended care, physicians should use electronic medical records (EMRs) to document their follow-up efforts, advises **Sharona Hoffman**, JD, LLM, co-director of the Law-Medicine Center at Case Western Reserve University School of Law in Cleveland, OH.

"The EMR will show when the doctor received the test result and when the patient had a next appointment," says Hoffman. In addition, doctors will order further tests and procedures through the EMR, so those tests and procedures will be reflected in the record.

The time and contents of any follow-up phone conversation with patients also should be documented, says Hoffman. "Doctors should be

very specific in their notes about what they told patients to do and whether they referred them to other specialists for care," she adds.

Emails between the physician and patient also will be retrievable and could serve as important evidence in litigation, says Hoffman.

A patient's failure to follow the physician's recommendations should be a strong defense in malpractice litigation, according to Hoffman. "As long as the instructions and test orders are clearly documented, and the patient understood what she was to do and chose not to do it, she will not have a strong malpractice claim," she says.

Send patients results

Patrick A. Malone, JD, a

Washington, DC-based attorney, says, "I have long advocated that physicians can show respect for patients' intelligence, and also protect themselves, by simply routinely sending copies of all test results to the patient."

Malone recommends that physicians forward all test results, along with a cover note to call the physician's office to set up a time to discuss the test results. "EMRs should make this easier to do, since the patient is only an email away," he says.

Then in the event of a missed followup, the patient will not be able to say "if I'd only been told." "But the even better result will be far fewer instances of followups falling through the cracks," says Malone. "Patients who are notified of abnormal test results will want to get to the bottom of them." ♦

Find out what the EMR does in response to plaintiff discovery request

The way information appears might surprise physicians

In one case involving the tragic death of an infant, the hospital's electronic medical record (EMR) automatically

changed the child's age to the date of the record's release. Documents received by the plaintiff attorney in

response to a discovery request referred to a 3-year old child.

"You can imagine how prejudicial

that would be," says **Reed D. Gelzer**, MD, MPH, founder of Trustworthy EHR, a Newbury, NH-based data quality and information integrity consultancy specializing in the legal aspects of EMRs.

"Most such instances conveyed to me involve hospitals or clinics that did not know what they were sending out the door in response to a records release request," says Gelzer. (See related story below on data integrity failures in EMRs.)

Medical-legally, EMRs are a "Pandora's box," says **Sam Bierstock**, MD, founder of Champions In Healthcare, a consulting company in Delray Beach, FL that advises hospitals, physicians and technology companies on implementing healthcare IT. "Most malpractice attorneys have not yet realized the depth of capability they have with EMRs. And when they do, we will have a major challenge," says Bierstock.

Physicians can consider these practices to reduce legal risks:

- Physician practices can test how the EMR would create a record in response to a discovery request.

"There are a number of amusing anecdotes about what the court has

Executive Summary

Physicians are using electronic medical record (EMR) functions that result in authorship falsification, disabling of audit logs, and document misattribution without understanding the legal implications.

- ◆ Some EMRs print information in a way that raises suspicions, such as dating a record when it was signed off on instead of when the patient was seen.
- ◆ Physicians can use comment fields to explain lengthy response times and overrides of drug alerts.
- ◆ Before accepting an order set, physicians should ensure everything is appropriate for the specific patient.

received, because nobody looked at it," says Gelzer. "[Providers] sometimes learn after the fact that really strange things occur."

Some EMRs print information in a way that appears suspicious, such as dating a record when it was signed off on, not when it originated. This issue could make it appear as though a patient was seen on a different date than actually occurred. "There is almost always a way to sort those things out. But what that immediately alerts an attorney to is they can't trust what they are looking at," says Gelzer.

Anomalies that appear to be red flags but turn out to be innocent mistakes can take many hours for attorneys

to sort out. "The last thing you want is something that diverts attention from your narrative of the facts," says Gelzer.

- Physicians should take advantage of comment fields to explain authorship edits, overridden drug alerts, delayed records entries, and to explain their thinking in the event of any intentional variances from established guidelines.

- Before accepting an order set, physicians should ensure everything is appropriate for the specific patient.

"The potential for liability is if the physician hits 'accept all' and submits orders without really reading them," says Bierstock. "There may be orders that don't apply to that patient." ♦

Data integrity failures in EMRs is No. 1 concern

Providers often use electronic medical record (EMR) functions that result in authorship falsification, disabling of auditing functions, and document misattribution without realizing the legal implications of these functions, says **Reed D. Gelzer**, MD, MPH, founder of Trustworthy EHR, a Newbury, NH-based data quality and information integrity consultancy specializing in the legal aspects of EMRs.

"People will do things in an EMR record that they would never do in a paper record," he says, such as copying information from previous visits and attesting to them being unique, new records, and deleting previous records or portions of records.

Data integrity failures with health information technology (IT) systems is number one on the ECRI Institute's top 10 patient safety concerns for healthcare organizations. (To download the full report, a slideshow, and a poster, go to <https://www.ecri.org/PatientSafetyTop10>.) The ECRI Institute is a Plymouth Meeting, PA-based nonprofit organization that researches approaches to improving the safety, quality, and cost-effectiveness of patient care.

"It is a shared clinical responsibility to reduce the risks of data integrity failures with EMRs," says **Karen P. Zimmer**, MD, MPH, FAAP, medical director of the patient safety,

risk, and quality group for the ECRI Institute's Patient Safety Organization. (An ECRI 2013 White Paper, "How to Identify and Address Unsafe Conditions Associated with Health IT" can be accessed at <http://bit.ly/1uQ6ReM>.)

Data integrity failures can occur for several reasons, such as data entry errors, missing or delayed data delivery, inappropriate use of default values, and copying and pasting. Zimmer offers these risk-reducing practices:

- Hospitals and physician practices should involve the end-user when determining default values. "It is crucial to have end-users and IT departments working together when implementing

new systems," says Zimmer.

- Physicians can avoid inadvertently entering data on the wrong patient by only opening one medical chart at a time.

- Organizations can provide an easy and accessible way for physicians to report problems when there are immediate issues, such as when data is not fully transmitted.

In a 2012 analysis, ECRI asked organizations to submit at least 10 safety events associated with health IT. "We learned there is under-reporting and lack of understanding when health IT may play a role in an event," says Zimmer. An event initially might be identified as a medication error, but further investigation might reveal there was a health IT component. Here are EMR charting

practices that might reduce physicians' legal risks:

- Functions that "bring forward" or duplicate from prior records must not be misrepresented as new records.

A statement such as "the patient's grandchild is at the bedside visiting" could be copied forward every day of the patient's admission, for example. "Those kinds of things are so easy to ridicule in a legal proceeding," says Gelzer.

- Functions that support one author "taking over" or editing the documentation of another professional must be used with full awareness and care.

The patient care record might make it appear there was a single author when multiple professionals actually provided the clinical services.

"At the least, the original version

of a licensed professional's clinical observations must not be incidentally obliterated or authorship 'reassigned' without preservation of the original content intact and accessible by some means," says Gelzer.

- Providers should never disable audit controls.

"This is similar to using correction fluid on a paper record. It demonstrates an ability and a willingness to alter records," says Gelzer.

Most clinical facilities assume that if the function exists in the system, it must be an acceptable one.

"However, EMR vendors are under no obligation to make sure that their systems comply with the laws of your state and the requirements of your insurers or any oversight agencies," says Gelzer. ♦

Inaccurate EMR charting can complicate the defense

A hospital recently found itself named as a defendant in a malpractice lawsuit brought by a patient following complications from spinal surgery, as a result of the surgeon's inaccurate electronic medical record (EMR) charting.

The day before a scheduled fusion surgery with spinal decompression, the patient developed an epidural hematoma. The surgeon waited for several hours to take in the patient for surgery to evacuate the hematoma.

"The delay was due to the surgeon wanting to do both the evacuation and the fusion in the same procedure and, as such, he had to wait until the spinal cord monitoring and other instruments could arrive at the hospital," says **Justin S. Greenfelder, JD**, an attorney with Buckingham, Doolittle & Burroughs in Canton, OH, who is defending the hospital.

However, there was no need for these instruments to simply evacuate the hematoma. In the EMR, the surgeon stated that the delay was due to a hospital policy that spinal cord monitoring be in place for all decompression

procedures. "This was not true," says Greenfelder. "The surgeon, who was not a hospital employee, attempted to mask his own poor decision, or potentially other motives, by blaming nonexistent hospital policies and procedures."

The surgeon also wrote in the EMR that "emergent request for expedition of this procedure was fraught with difficulties from policies and procedures."

"Again, this was not true, as the surgeon had refused to take the patient in to surgery earlier despite the availability of personnel and an operating room and a direction from the head of the department to proceed with the evacuation," says Greenfelder. In fact, there was no hospital policy that prevented the patient from being taken to surgery emergently to evacuate the hematoma. The patient suffered terrible complications and died a few months later.

"This false entry in the EMR by the surgeon was the reason the hospital was included in the malpractice/wrongful death action," says Greenfelder.

The plaintiff's counsel indicated that he did not believe the surgeon's accusation but, because the surgeon had put

these statements in the EMR, he was compelled to include the hospital in the suit. The case is currently stayed, as the surgeon has filed for bankruptcy.

"Although I am confident that the hospital will be extricated from this case, the spine surgeon's statements in the EMR led the hospital to incur costs of defense that should never have been incurred," says Greenfelder.

Inaccurate drop-down charting

In a recent malpractice suit against an obstetrician, nurse midwife, and hospital, the obstetric nurse's drop-down entries, which were later claimed to have been done in error, made the case more difficult to defend.

Robert D. Kreisman, JD, a medical malpractice attorney with Kreisman Law Offices in Chicago, says, "I believe the principal reason the hospital and nurse midwife were inclined to resolve the case by settlement were those entries that they maintained were not accurate."

While drop-down charting is becoming the norm, says Kreisman, it

is not uncommon that clerical errors can be damaging to a physician's defense. "Particular attention should be given to those entries," he advises.

Once it's proven that part of a medical chart is not accurate, says Kreisman, "that burden is a difficult one to overcome in many cases."

Kreisman routinely requests EMR "audit trails" from defense attorneys, as a way of tracing the medical provider history for the patient during a hospital course. "The audit trail or audit log tends to be in chronological order, and in most cases, shows the computer entry of any medical provider taking care of a hospital patient," he says. Kreisman uses the audit trail in these ways:

- to find out who had access to the EMR, and the time and date the records were accessed;
- to identify which doctors, nurses, and others reviewed diagnostic tests;
- to learn who entered test results

Executive Summary

Inaccurate electronic medical record (EMR) entries have complicated the defense of some malpractice cases.

- ◆ EMR charting can result in additional defendants being named.
- ◆ Otherwise defensible cases have been settled.
- ◆ Inaccurate drop-down charting can damage a physician's defense.

or medical information on a particular patient.

"The audit trail is very important in medical negligence cases, to show whether or not a physician reviewed or did not review a diagnostic such as an MRI or an X-ray," says Kreisman. "This could be important in the outcome of the case."

Steven M. Levin, JD, founder and senior partner at Levin & Perconti, Chicago, says EMR charting is "easy to read, but difficult to interpret." The healthcare practitioner's thought process is often missing, and the same

information often is repeated again and again. Still, says Levin, "any data you have access to that can benefit your clients case is well worth the time and effort required to properly 'mine' it. When EMRs are available, we will always request them."

If Levin discovers that a record was deleted, falsified, or changed after the fact, this action triggers further investigation. "We frequently see record falsification in nursing home negligence cases, and the electronic trail confirms our suspicions," he says. ♦

These EMR shortcuts are legally risky for MDs — Workarounds can complicate defense

Some electronic medical record (EMR) features result in physicians "getting a little careless on what seem to be trivial issues, but which can come back to haunt them," says **Robert J. Milligan, JD**, an attorney at Milligan Lawless in Phoenix.

Instead of using "workarounds," advises Milligan, physicians should address the problem with the EMR vendor or the hospital's information technology (IT) department.

Some plaintiff attorneys are videotaping physician depositions using two screens: one shows the physician, and the other shows the record the physician is looking at. "So if the physician used a workaround, that's going to be highlighted in fairly dramatic fashion," says Milligan. Here are some examples of EMR charting practices that can complicate a physician's defense:

- Being careless with drop-down boxes.

Some EMRs ask physicians if they've asked the patient about tobacco use. Unless physicians click on "yes," they can't go on to the next field. "Physicians have to ask the question, or cheat, by clicking the box that says 'yes,' and moving on," says Milligan. "Cheating may be easier, but it's never the right solution."

- Failing to review information carried forward from one patient interaction to the next.

A pregnant patient being seen for an ear infection might have a note carried over from a prior visit about an abdominal examination, for example. When questioned about the visit in a legal proceeding, the physician then has to admit he or she did not really examine the patient's abdomen as the

record indicates.

"Now you've tainted the whole record, because you admitted that something your note says you did, you didn't really do," says Milligan. "You have now told us that the record of what you did is not completely reliable. That's a pretty bad place to start."

To reduce risks, physicians shouldn't carry information forward unless the prior notes are reviewed and found to be accurate, with a notation stating, "Following information is from prior visit, which is all still in effect," advises Milligan.

- Failing to include medical decision-making.

"This is often the critical element in a malpractice case, a state medical board review, or even a billing audit," says Milligan. If the physician's decision-making isn't evident in the EMR,

Executive Summary

Some electronic medical record features can result in physicians using "work-arounds" to streamline documentation, but these actions can be legally risky. Plaintiff attorneys look for indications that physicians:

- ◆ carelessly checked drop-down boxes
- ◆ failed to review information carried over from previous visits;
- ◆ failed to indicate that a certain diagnosis was considered.

the plaintiff expert can infer that the physician didn't consider a particular issue.

"I have heard experts say, 'If the defendant physician had considered X, Y, and Z, and made a judgment call, I would not be critical. But according to the record, the physician never even gave that any thought,'" says Milligan. The physician's insistence to the contrary, now that he or she is a defendant in a lawsuit, is likely to appear self-

serving.

- Failing to realize that EMRs auto-populate fields.

"This is not always clear to the provider," says Michelle M. Garzon, JD, an attorney at Williams Kastner in Tacoma, WA. "Automatic fill-ins are viewed as a time-saver, but they can get providers into trouble if they're not thoughtful."

During litigation, physicians are sometimes surprised to see that the

EMR printout automatically checked off boxes for things that weren't done for that particular patient.

The EMRs might indicate that bilateral pulses are "within normal limits" even in a patient with an amputated foot, for example. "It's within normal limits for the person, so the provider doesn't check anything. But it comes out as showing that they did," says Garzon.

If the EMR has "within normal limits" as the default, the plaintiff attorney is likely to ask the physician whether he or she went through each box before checking it. "If the physician only puts in the abnormalities, then it's hard for them to say, 'I did all those things,'" says Garzon. (See related stories on why IT expertise is needed to explain EMR charting below, and trends in e-discovery, p. 9.) ♦

Both sides need IT expert to explain EMR charting

Requests for metadata are increasing the cost of malpractice litigation, because it requires that attorneys invest time and money to determine its meaning.

"Once the defense presents the metadata, it's not going to necessarily be in English. You need somebody to decipher it," says **Thomas R. McLean**, MD, JD, CEO of American Medical Litigation Support Services, a Shawnee, KS-based firm that provides attorneys with litigation support.

Attorneys are increasingly hiring information technology (IT) experts to help with this. "On the defense side, once you receive notice that something is going to be litigated, then you have an obligation to preserve the evidence," says McLean. One question is how much of the metadata in the patient's medical record has to be preserved. "Theoretically, it's all of it," says McLean. "But this could be viewed as unduly burdensome. These are questions that have to be worked out down the line."

Defense lawyers might need to hire an IT expert to decipher what the metadata shows. **Michelle M. Garzon**, JD, an attorney at Williams Kastner in Tacoma, WA, says, "I can't keep it back from the plaintiff, but I sure want to know what it's saying before I turn it over."

Even the wording used for discovery requests varies depending on the EMR system used by the physician practice or hospital. "There is a learning curve on how to request it, how to get it, and how to determine if it exists," says McLean. "You might have to depose the IT guy to get at this stuff. The Cerner data might not be the same as the Epic data or the VA's EMR."

IT experts can help the plaintiff to prepare discovery questions and interpret what is received in discovery, and in some cases, might even testify in court.

In this case, says McLean, "you will need a highly articulate IT person. Otherwise, a good defense attorney is going to show that the person is confused and doesn't know what they are talking about."

Suspicions are raised

EMRs give the defense the added job of explaining to a jury why the printout they're viewing appears very different from what the provider viewed onscreen while caring for the patient.

"We have been trying to get a beta version from the EMR vendors to use in depositions, because it looks so different in the printout than it does to the providers," says Garzon.

A one-week admission might produce 1,000 pages with a lot of duplication. "Sometimes you can print it out one day, and if you print it out again the next week, it looks different," says Garzon. "That raises suspicions."

The plaintiff might have obtained EMR charting in a particular way in a previous case, but the information isn't available in the same way for a subsequent case because the defendant uses a different EMR. "This requires an explanation of how the system works," says Garzon, "Otherwise, they think you are hiding something." ♦

Plaintiff attorneys doing more e-discovery, but it's not always fruitful

Many plaintiff attorneys now routinely request metadata from electronic medical records (EMRs), but in some cases, it ends up helping the defense.

"When you sort it out, it could hurt the provider. Maybe he looked at the EKG but didn't do anything about it for two hours. But it can also support the doctor's testimony," says **Michelle M. Garzon, JD**, an attorney at Williams Kastner in Tacoma, WA.

In a recent malpractice claim, a patient called an outpatient clinic to report continuing chest pain and was told to come in for a stress test. "The plaintiff had a massive heart attack before he was able to get in," says Garzon, who represented the clinic in the ensuing lawsuit.

"The plaintiff attorney was digging around in the EMR to see what the doctor knew when," says Garzon. The claim against the clinic was dismissed, after EMR entries showed that the nurse had appropriately conveyed the calls to the physician.

The way in which metadata affects the outcome of a suit can be surprising. "It may create a problem for the defense that wasn't there previously," says Garzon. "Or it could, hopefully, answer the plaintiff's question and make a suit go away."

Metadata requests vary

The plaintiff attorney can obtain only whatever metadata exists at the time the suit is filed, notes **Thomas R. McLean, MD, JD**, CEO of American Medical Litigation Support Services in Shawnee, KS.

"To save metadata requires memory that you have to pay for, and

especially for a physician's office, that's one way to reduce costs," McLean says.

If the suit is filed just under the statute of limitations which is typically two years, it's possible that the metadata already has been lost through the course of normal usage.

How much metadata plaintiff attorneys obtain depends in part on the way the discovery request is worded. "Sometimes they ask for the entire admission, which we would usually object to as overly burdensome," says Garzon.

Even hospital medical records departments don't always understand what's contained in the EMR, which makes it difficult for the defense to respond to discovery requests.

"Getting answers on what they have is sometimes hard, even with big sophisticated hospitals," says Garzon. "I usually have to get an IT contact." Garzon is aware of one case in which defense attorneys had to obtain a declaration from an EMR vendor to explain why the printout appeared differently from the on-screen version.

"One of the more interesting questions is, 'What is the EMR?'" says McLean. "I think there's a good argument that it also includes any electronic device that a patient may be hooked up and monitored with." For example, the anesthesia record isn't typically preserved electronically along with the metadata it contains.

"But that information still exists when the suit is filed, potentially, depending on how much storage space machines have," says McLean. "As we go forward, physicians can be tripped up because

they don't realize that these devices also store data."

The "old-fashioned" way

Some plaintiff attorneys choose not to delve into EMR metadata because it's outside their comfort zone.

"If their careers have been in paper, they are happy to try the case the old-fashioned way," McLean says. "The Facebook generation of attorneys will have a whole different view of how to conduct a case using electronic evidence."

In other cases, plaintiff attorneys ask for metadata to answer a specific question, such as how long the physician stayed on the screen when an alert came up. "If it's a short click, that would be more damning," says McLean. "That's a situation where you might be willing to pay to do a focused metadata discovery, in order to impeach the physician."

However, McLean says a tried-and-true approach can get the same result by questioning the hospital's pharmacy director as follows:

"Does your EMR put up warnings for indications of drugs? Is Drug A in your formulary? If I tried to prescribe it, will there be an alert that comes up? Can you describe it?"

If the director testifies that the alert says not to give the drug to anyone under 5 years old or it can be fatal, and the physician gave the drug to a 4-year-old, "that's going to make the physician look bad," says McLean. "You can do it without going after the metadata. You certainly don't need an IT guy for that." ♦

Sunshine Act reporting has implications for malpractice litigation

Under The Physician Payment Sunshine Act, manufacturers of drugs, devices, and biological and medical supplies are required to report payments made to physicians to the Centers for Medicare and Medicaid Services. This data, once it is posted on a public website in September 2014, could help plaintiff attorneys to strengthen malpractice claims.

"Many physicians and practice managers do not realize that the net is very broad. Even being taken out to lunch is going to be reportable," says **William M. Mandell, JD**, an attorney with Pierce & Mandell in Boston.

A plaintiff attorney could argue that a physician's relationship with industry is relevant to a claim that the physician committed professional negligence. "In some malpractice cases, there could be an inference or circumstantial evidence that the physician's independent judgment was clouded by financial relationships," says Mandell.

Nothing in the statute or the implementing rules prevents the data from being used in court. "So, the informa-

tion will be out there, and it really all just depends on the rule of relevancy," says **Christopher Robertson, PhD, JD**, associate professor at the University of Arizona's James E. Rogers College of Law in Tucson.

While the easy availability of the database will increase the likelihood of plaintiffs' attorneys checking it as part

subpoena to the manufacturer. "There is a wealth of publicly accessible data already on physicians and industry," says Mandell. "Many of the larger pharmaceutical companies, as part of settlements with the government on false claim cases, or even voluntarily, have put up their data to get ahead of the curve."

Some states have had transparency laws in place for several years requiring manufacturers and distributors of pharmaceuticals and devices to report certain transfers of value of payment to doctors licensed in the state.

"The Sunshine Act is not necessarily going to be that revolutionary or dramatically different than what's already been publicly accessible, but will be a more comprehensive and easily searchable database," says Mandell.

Relevancy is issue

To use a physician's financial relationships as evidence, the plaintiff's attorney has to show the judge why the payment is relevant.

"I do not think that many judges will allow the payment alone to tar the doctor," says Robertson. However, if the plaintiff's attorney can tie the payment to the specific clinical decision that the physician made, then it might be admissible.

"Such a payment may show bias: that the physician erred on the side of prescribing, when he or she really should not have done so," says Robertson. A significant financial relationship could open up the physician to punitive damages, if the attorney can show an ulterior financial motive behind the prescribing decision.

"Physicians may be able to better defend such claims if they also make disclosures directly to patients, at the point when the patient is making

In some malpractice cases, there could be an inference or circumstantial evidence that the physician's independent judgment was clouded by financial relationships.

of their due diligence investigation of a claim, says Robertson, "in another sense, there is nothing new here."

Even before the act, a plaintiff's attorney could have always gotten the information through civil discovery by asking about it at deposition, requesting production of documents, or via

Executive Summary

Publicly reported data on payments made to physicians will be available in September 2014, as a result of The Physician Payment Sunshine Act. This could help plaintiff attorneys to strengthen malpractice claims.

- ◆ There could be an inference or circumstantial evidence that the physician's independent judgment was clouded by financial relationships.
- ◆ To use a physician's financial relationships as evidence, the plaintiff's attorney has to show that the payment is relevant.
- ◆ A significant financial relationship could open up the physician to punitive damages, if the attorney can show an ulterior financial motive behind the prescribing decision.

the ultimate treatment decision," says Robertson.

Financial motives to prescribe

Physicians with financial ties to drug and device companies might be more likely to prescribe those companies' products to their patients, says **Stephanie M. Godfrey, JD**, an attorney in the Philadelphia office of Pepper Hamilton.

"If physicians are overprescribing products or prescribing products that are not medically necessary for patients, the risk of patient harm and medical malpractice increases," she says.

The Sunshine Act database might reveal a financial tie to a company whose product is allegedly connected to the patient's injury. "A patient and his or her attorney may view the information as evidence that the physician's motivation to prescribe the product was based on financial considerations and not the best interests of the patient," says Godfrey. This situation is true even if a physician's prescribing habits are entirely appropriate and

in accordance with accepted medical standards, she adds.

"Such information can be used to support a claim that the physician overprescribed products, or was negligent in prescribing products because of the financial incentives received from manufacturers," says Godfrey. She says physicians should do these things to protect themselves legally:

- Adhere to applicable state and federal disclosure requirements.
 - Keep detailed documentation regarding the medical necessity of any products manufactured by companies with which the physician has a financial relationship.
 - Consult with an attorney to make sure such arrangements comply with applicable healthcare laws, such as the federal Anti-Kickback Statute and Stark Law, and analogous state laws.
- "To the extent such arrangements contain unlawful payments in exchange for referrals, physicians could also be prosecuted for violating fraud and abuse laws in addition to being sued for medical malpractice," warns Godfrey. ♦

Will apology cause patient to sue? Perception is 'outdated and inaccurate'

(Editor's Note: This is the second story in a two-part series on apology laws. This month, we report on how a physician's apology could affect the outcome of a malpractice suit. Last month, we covered a recent court ruling distinguishing between apologies that express sympathy and those that acknowledge fault.)

Evidence shows that "apology" laws "have done much more good than harm," says **Benjamin Ho, PhD**, assistant professor of economics at Vassar College in Poughkeepsie, NY. A 2011 analysis estimated that apologizing to a patient would reduce the average medical malpractice payout by \$31,000.¹

"States that passed such laws saw settlement speeds increase by 20%, especially in the most severe cases, where settlement amounts decreased by 14% to 17%," reports Ho, one of

the study's authors.

The biggest predictor of whether a patient sues is the relationship between doctor and patient, according to Ho, "and apologies go a long way in restoring trust in that relationship." On the other hand, apologies also might alert the patient to the nature of the error. "Therefore, apologies could increase the likelihood the patient seeks legal counsel," acknowledges Ho.

The perception that an apology will cause a patient to sue is

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“outdated and inaccurate,” argues **Doug Wojcieszak**, founder of Sorry Works!, a Glen Carbon, IL-based company that trains healthcare providers in disclosure. The physician’s apology has the potential, through an admission of guilt, to be used by an injured plaintiff as evidence to support two elements of a malpractice case: breach and causation. “A doctor should not be admitting fault until a review has proven a medical error,” says Wojcieszak, and instead, a physician should make only empathetic statements such as, “I am sorry this happened. We will be doing a review and report back to you.”

“Every doctor since medical school has been told if they apologize it will be used against him,” adds Wojcieszak. “But if an apology is all the plaintiff has to hang his hat on, that’s not much of a case.”

Confusion over what laws cover

Most state “apology laws” cover

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only expressions of empathy or sympathy, though some states, including Connecticut, Georgia, South Carolina, and Colorado, go further and include expressions of liability. However, “some of the best disclosure programs operate in a state with no apology law in the books,” says Wojcieszak.

“There is confusion in the field about what the laws cover,” he says. “But whatever form they are in, they will encourage doctors to disclose.”

Many plaintiff attorneys, in fact, would be reluctant to make an issue out of the fact that a physician apologized to a patient, he adds. In some cases, defense counsel want to call attention to the apology. “They say, ‘I don’t care what the laws say, I’m going to get this into the record before the jury because it’s going to humanize my client. It’s going to make my client look good,’ ” Wojcieszak says.

When selling their practices to hospital systems, physicians should inquire about disclosure practices,

he advises. “If three competing systems all want to buy a practice, they’re all going to pay about the same,” says Wojcieszak. Physicians can differentiate between them by asking questions such as, “Do you have a disclosure program? How does it work? How will you support me, my colleagues, and my patient and family post-event?”

Physicians typically assume, sometimes wrongly, that insurance companies and hospital risk managers are against physicians apologizing to patients.

“So many doctors just work off what they heard 20 years ago,” Wojcieszak says. “Don’t make assumptions. The time to find out about this is now, rather than when an adverse event happens.”

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- Ho B, Liu E. Does sorry work? The impact of apology laws on medical malpractice. *J Risk Uncertain* 2011; 43(2):141-167. ♦

Physician Legal Review & Commentary



A Monthly Supplement to PHYSICIAN RISK MANAGEMENT

Man with spinal injuries commits suicide — \$2.88 million verdict given

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News: The patient, a 40-year-old man, sought treatment in May 2008 for chronic lower back pain at a pain clinic operated by two physicians. The initial treatment, which consisted of medication injections into the patient's back, was successful for a time, but the patient returned to the clinic three more times seeking further pain relief. After the third set of epidural steroid injections, the patient developed swelling at the injection site and allegedly told the physician this information before receiving his fourth injection. However, the physician continued

with the injection, which passed through the infected, swollen area and contaminated the patient's spinal cord. The patient's condition deteriorated quickly: He was diagnosed with meningitis caused by methicillin-resistant *Staphylococcus aureus* (MRSA). The patient survived, but with serious spinal injuries. The patient brought suit against the physician and clinic, but the patient took his own life before the case was heard in court. His parents and estate continued the suit, and the jury found the physician and clinic liable, awarding \$2.88 million in damages.

Background: In this matter, the patient was an active 40-year-old man who suffered from chronic lower back pain. He sought treatment from a pain clinic operated by two physicians, both certified in anesthesiology and pain management. In May 2008, the patient received a first set of medication injection into his back, which was temporarily successful at relieving his pain. He returned in December for another round of injections, done by the same physician as the first round. This second set of injections was less successful, and the patient

visited the clinic again in January for more treatment. The original physician who performed the first two treatments was out of town, so the second physician attended to the patient this time. This second physician gave the patient an epidural steroid injection (ESI) in his lower back.

The injection did nothing to relieve the patient's pain; however, swelling and a lump appeared at the injection site. The patient returned to the pain clinic eight days after this third round of injections and was attended to by the second physician again. What happened at this visit was debated during trial. The patient alleged that he told a nurse about the swelling, who then talked to the physician and reported back that the lump was not a problem. The physician claimed to have never heard about the swelling, and it was not mentioned in the patient's medical records, thus it did not exist. Regardless of which version is true, the physician continued with another injection. Standard practice is that there is at least a two-week waiting period between steroid injections, so this fourth injection was very unusual, given that there can be serious side effects without further review and discussions with patient

and peers. The medical record did show, however, that the entire procedure for this injection was done in three minutes. The patient's condition deteriorated quickly after the injection: His pain increased, and he was nearly immobilized. He was taken to an emergency department where he was diagnosed with an epidural abscess, deep tissue infection, and meningitis caused by MRSA. Surprisingly, after about 10 days of treatment, the patient pulled through the serious infection, but he was left with severe spinal injuries, impotency, loss of control of his bladder and bowels, difficulty walking, and constant pain.

The patient brought suit and alleged that the second physician's final injection was negligent due to the existing lump, which was a sign of infection, and this infection was spread to the spinal cord from the injection. The patient took his own life before the case made it to trial. His parents and estate continued the suit and blamed the suicide on the underlying medical condition brought about by the negligence of the defendants. The physician and clinic defended on the basis that the patient had a history of psychiatric issues that led to the suicide, not the underlying medical condition brought about by negligence. The patient had a history of bipolar disorder and had admitted himself to psychiatric care for treatment of depression in the past. His parents claimed that these psychiatric issues were under control in the recent past. After two days of deliberation, the jury returned a verdict for the plaintiffs and awarded them \$2.88 million, most of which went to the patient's estate. The jury found the physician to be 75% at fault and the clinic to be 25% at fault.

What this means to you: This case illustrates the dangers of infections and failing to recognize their signs and symptoms. There were multiple problems that occurred and resulted in the serious injuries that the patient suffered: The third injection caused an

infection, and the fourth injection spread the infection from the site to the spine, which dramatically increased its harm. Physicians must follow proper safety procedures to prevent infection from occurring in the first place. The Center for Disease Control and Prevention (CDC) has identified that injections pose particular dangers when it is a spinal injection. Cases of bacterial meningitis have been identified in patients undergoing spinal injection procedures that require injection of material or insertion of a catheter into epidural or subdural spaces. These situations apply to any location where a physician might be for a spinal injection, and the CDC particularly recognized the need for caution at pain management clinics.

The CDC has specific recommendations for physicians performing spinal injections as relating to infection prevention: Facemasks should always be worn, and aseptic technique should always be followed. For example, physicians should use a single-dose vial of medication or contrast solution for only one patient, as well as ensuring that needles or syringes are not reused for different patients. Injection sites must always be properly cleaned before proceeding, and if there are any abnormalities, these should be examined and caution should be observed.

Before performing any procedure, physicians should examine patients and look for any signs or symptoms of infection. If the patient has a fever or unhealed skin sores, this might be a sign, and the physician should consider whether or not to postpone an injection or operation. A patient who already has an infection will have a more difficult time recovering and might suffer even worse adverse effects from the operation. A physical examination, combined with a review of the patient's

medical record, is the only way to accomplish a complete assessment of the patient's current status. Using both processes ensures that anything omitted from the record, such as a nurse's conversation with the physician about the lump at the injection site, would be discovered on physical examination. The physician here completed the injection in a mere three minutes, which is hardly enough time to consult and examine the patient thoroughly to determine if the procedure is proper.

Communication is extremely important, and physicians need to listen to communications from nurses and patients. Each of these parties can have vital information that physicians might need to perform proper diagnosis and treatment of patients. If these communications are ignored or never occur, there is a danger that this information will be lost. A physician acting without being completely informed is at risk.

Defending on the basis of the medical record alone might be a difficult, if not impossible, proposition. Physicians are wise to consult a patient's medical record, and they should do so before diagnosing or treating a patient. However, medical records are not infallible, just as the humans who create the records are not infallible. Mistakes happen, and for whatever reason, a particular condition or symptom might not make it into the patient's medical record. Relying on this document exclusively is thus dangerous, as the physician here learned: He claimed that, "If it's not in the record, it didn't exist." What is understandable is that physicians are not required to remember the details of every procedure from the time of the procedure to the time of trial, especially since it might be many years before a trial occurs. The absence of information from a medical record does not necessarily mean that the event or condition did not happen, as it may have been

a simple oversight or mistake in the recordkeeping. Here, if the physician had examined the patient for signs of infection, he could have recorded this positive examination and noted that none were found, which would

have been a much stronger defense than simply stating that it didn't exist since it wasn't in the record. Medical records are a multipurpose tool for physicians, as they can be used in the actual treatment of patients and in

their own self-protection this way during trial.

REFERENCE:

1. District Court of Johnson County, KS. Case No. 10CV11069. April 14, 2014. ♦

Woman receives \$14 million verdict in Yasmin prescription case

News: The patient, a 37-year-old woman, was prescribed the oral contraceptive pill Yasmin by her physician in an attempt to control irregular bleeding. Thirteen days after she began taking the medication, she suffered a stroke that resulted in serious brain damage. The patient was left partially paralyzed on her left side and suffers from speech problems, among other permanent injuries. The patient brought suit and claimed that the physician knew or should have known that she had an increased risk of stroke due to pre-existing risk factors for birth control pill blood clots. The physician denied any wrongdoing. The jury found the physician liable and awarded the patient \$14 million in damages.

Background: The patient was a woman who consulted her physician about irregular bleeding she was having. The physician prescribed the oral contraceptive pill Yasmin (drospirenone and ethinyl estradiol), manufactured by Bayer HealthCare Pharmaceuticals. Yasmin contains drospirenone, a synthetic form of the naturally occurring female hormone progesterone, and it is one of the most popular oral birth control products, along with a newer version sold under the brand name Yaz. Yasmin and Yaz have been the subject of controversy and lawsuits over the past few years. Medical professionals allege that the medications have severe adverse side effects,

including heart attacks, strokes, pulmonary embolism (PE), and deep vein thrombosis (DVT). Last year, the Food and Drug Administration (FDA) issued a safety review update for Yasmin and other birth control drugs containing drospirenone, including Ocella, a generic version of Yasmin. Medications with drospirenone have been found to triple the risk of blood clots in patients. The FDA review specifically recommends that "[h]ealthcare professionals should consider the risks and benefits of drospirenone-containing birth control pills and a woman's risk for developing a blood clot before prescribing these drugs." For more information, see <http://www.fda.gov/drugs/drugsafety/ucm299305.htm>.

Thirteen days after beginning to take the medication, the patient suffered a stroke, which resulted in serious brain damage. She was left partially paralyzed on her left side and must use a wheelchair, along with suffering from speech problems. The patient now requires round-the-clock care, which her husband has been providing since the accident and is thus unable to work himself. The patient brought suit against the physician and medical center that referred her to the physician, and she alleged that the physician knew or should have known that the patient had an increased risk of suffering a stroke on Yasmin due to pre-existing risk factors for birth control pill blood clots. The patient also claimed that the physician did

not tell her about the risks associated with Yasmin.

Prior to the case going to trial, the medical center settled for \$2.5 million. The physician denied any negligence, and he claimed that he did not have actual knowledge about the patient's underlying risk factors contributing to the blood clot. A two-week trial resulted in a verdict for the plaintiffs, with the jury awarding \$14 million to the injured patient and her husband caretaker.

What this means to you: The primary issue in this case was whether the physician fell below the standard of care in prescribing the patient this particular medication. A physician can be found negligent if reasonable physicians, given the same or similar circumstances, would not have prescribed the medication for several reasons. The most important reason in this case was the particular patient's pre-existing risk factors, which pose potentially deadly consequences when combined with the known side effects of the medication. For physicians, this means that there are two important concerns that are shown in this case: Physicians must be aware of a patient's particular medical and family histories and pre-existing risk factors, and physicians must be informed about medications they are prescribing and the potential side effects.

Knowledge of a patient's medical and family histories is extremely important in many aspects of a physician's work. On an individual level, a particu-

lar patient might have had past occurrences that have future consequences on the patient's overall health, such as increasing the chances that an otherwise rare event might happen. Blood clots are one such event, and they occur more frequently in patients with particular characteristics: smoking, obesity, diabetes, elevated cholesterol, etc. This situation is especially relevant to blood clots caused by hormonal birth control, which is a known side effect of hormonal birth control. Beyond the individual patient, however, physicians should inquire into the patient's family history. Family history might reveal further information that is highly important to diagnosis, prescriptions, or treatment. There are numerous genetic disorders that are passed down in a family history but might not display any signs or symptoms, thus a patient might be unaware that the patient has the condition.

When posed with these decisions, physicians should have the patients inquire about their own personal family history in addition to running tests that can determine such latent conditions.

For another illustration of the importance of medical and family histories, consider that there are a number of genetic blood clotting disorders. One is factor V Leiden, the most common genetic condition that can lead to blood clots. According to Children's Hospital of Los Angeles a person with factor V Leiden has 10 times an increased chance of developing a blood clot. Moreover, a person on hormonal birth control has about three times an increased chance of developing a blood clot. The combination of factor V Leiden and hormonal birth control thus increases the risk of getting a blood clot by 30-40 times that of an average, healthy individual. Thus, a 16 year-old girl who has factor V Leiden, if put on the hormonal birth control pill, has a risk of roughly 1 out of 1,600 for developing a blood clot whereas a healthy teen-ager not on the birth control pill enjoys only what is roughly a 1 out of 50,000 chance. A patient's specific family history is

an invaluable tool here since factor V Leiden is passed down from a child's parents. It is more common among families with ancestry in the Middle East, but it also occurs in families with ancestry in Europe.

Along these lines, physicians can add an extra layer of protection by having patients sign a statement of patient responsibilities' along with patient rights, and included in this statement is the patient's responsibility to provide the complete medical and family history as requested. Because patients might omit critical information purposefully to obtain certain medications or treatments, this statement can aid a physician in protecting oneself. A physician who does not inquire about the patient's family history, or run appropriate tests to determine these potential risk factors, might be negligent if reasonable physicians in the same position would inquire. These kinds of questions are simple to ask patients and have potentially huge consequences if left unanswered.

Physicians must be informed about the medications they are prescribing, especially side effects, which might have serious detrimental results. The pharmaceutical industry is a booming giant, with innumerable medications already in existence and new medications consistently being introduced. The Food and Drug Administration (FDA) is responsible for approval of prescription drugs, and it is an invaluable source of information for any physician. The FDA's website (www.fda.gov) has an overwhelming amount of information, including drug safety information and recall information. FDA still might approve medications that can have serious, dangerous side effects. A physician can be responsible for prescribing an FDA-approved medication when it is given in the wrong circumstance, such as when a patient has other risk factors which, along with the side effects, might cause harmful consequences to the patient. Yasmin has had a black box warning, the FDA's strongest warning,

since 2003. These warnings must be reviewed, and recommendations for safe prescribing must be followed. Physicians also can seek information from the drug manufacturer, and many manufacturers take a proactive approach by using sales representatives to seek out physicians to inform and persuade them to prescribe their drugs to patients. Because this field is a competitive, billion-dollar industry, pharmaceutical companies might take this offensive approach to informing physicians, but physicians should be cautious in relying solely on a pharmaceutical company's representations. The company has an obvious interest in promoting its medications.

When prescribing a patient medication, physicians should inform the patient about the side effects to fully inform the patient before they choose which to take. There might be a number of different medications that have the same positive effect but have lesser or varying side effects, and physicians should consult with the patient before choosing any single medication. Patients might have concerns of their own or want to stay away from specific side effects for their own reasons. If the patient is not specifically told about a medication's side effects, the patient might simply assume that there are none. Furthermore, informing patients of the side effects will allow them to recognize potentially dangerous symptoms to ensure that if something does happen, the patient can identify this symptom and seek treatment immediately. Physicians who fail to inform patients before the patient makes an important medical decision might be liable for negligence, if reasonable physicians under the same or similar circumstances would fully discuss and inform patients about their options and the effects of their choices.

REFERENCE:

Circuit Court of Cook County, IL. Case No. 2009-L-4061. April 14, 2014. ♦