THE scpie COMPANIES

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Drug Samples: Accountability and Control Are Essential to Reducing Liability Risk

IN THIS ISSUE

Sample medications can benefit patients by saving them money, thereby strengthening the goodwill they feel toward their physician. But when a medical practice's management of samples (or any other medications) becomes too informal, the laxity can put the physician, office staff and patient at risk.

Drug samples often move from drug rep to office staff to physician without documentation or accountability. The liability risk issues involved include lack of appropriate tracking (and the problem of theft it can facilitate), dispensing of meds that are not in childproof containers and inattention to expiration dates.

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requires that medical institutions have a policy and procedure related to the control of drug samples, and that such samples be handled with the same level of accountability and security as other prescription medications.

Consider the following guidelines when handling drug samples:

- Store, secure and track samples to prevent needless access and loss.
- Document the dispensing of samples in the patient's medical record.
- Obtain and document informed consent from the patient.
- Label samples with prescribing information.
- Regularly monitor samples for upcoming expiration dates.
- Maintain records so patients can be contacted if the medication is recalled. ■

Lawsuits by Drug Trial Participants on the Rise

According to a report in *Business Insurance* magazine, a growing number of participants in clinical drug trials are filing lawsuits, often claiming they did not receive adequate warning about possible risks.

Some of the lawsuits name as defendants physicians involved with the trials—in addition to pharmaceutical companies, manufacturers of medical devices and institutions where the trials were conducted.

Media attention could be one factor in the trend, said George Mernick, a defense attorney with the Washington, D.C., law firm of Hogan & Hartson. "There have been enough cases now that have received some measure of publicity, that like any trend in litigation, a few cases can tend to spark a lot of cases," he observed. Another factor: growth in the number of clinical drug trials, which currently number 50,000 in the U.S. alone. ■

Practicing Medicine by Phone Or E-mail—Physician Beware!

The telephone and computer can be the most useful communication tools in your medical office—but practicing medicine by phone and e-mail is risky. Telecommunications healthcare cannot replace face-to-face healthcare.

Diagnosing medical conditions without examining a patient does not allow assessment of the person's appearance, body language, severity

of symptoms or other factors normally considered during a physical exam. Some patients—or some of the individuals who call in on their behalf—may be unreliable or inaccurate when assessing a problem or describing symptoms. Such inaccuracies can have serious consequences.

Only a few years ago, telemedicine appeared to be healthcare's next big trend; a number of companies and solo physicians rushed to offer telemedicine services. Even though the companies advertised that they would provide over-the-phone medical care (including prescriptions) 24 hours a day, seven days a week, many of them had trouble convincing patients that remote consultations were a good idea.

A significant segment of the medical community remains deeply skeptical that doctors can adequately treat patients they have never seen in person. The American Academy of Family Physicians strongly opposes the idea, and the American Medical Association has expressed concern that patients who are treated over the phone could get shortchanged and even harmed. The Medical Board of California asserts that companies offering telemedicine services may be violating state law by allowing doctors to treat patients by phone.

Despite all that, it is undeniably true that the telephone and computer have become indispensable tools for today's medical practices. Given the potential risks involved, however, it is essential that these tools be used properly.

Documenting Patient Phone Calls

When it comes to phone conversations with patients—whether they involve you or members of your staff—what information needs to be recorded in the patients' charts?

Calls are made to physicians' offices for a variety reasons—from making, canceling or rescheduling appointments to inquiring about test results to checking on the status of an outstanding bill. It is not necessary to record details of all of these calls in the medical record, but a system should be in place to confirm that each call was responded to.

Documentation requirements do kick in, however, whenever a call focuses on conditions of medical care. This type of call must be documented in the medical record; the notation should include the nature of the inquiry, the person to whom the caller was referred, a tentative diagnosis and the action plan established to resolve the issue.

A brief note should be jotted down even when

the call comes in the middle of the night—or, say, when you're attending your child's school pageant. A more extensive note can be written or dictated into the medical record the next day.

If a prescription is given via the telephone, it is critical that there be a well-documented notation in the permanent medical record. The amount of the prescription should be minimal, and the patient should be instructed that an office visit is imperative prior to any further prescribing.

Patients who view telephone calls as a convenient alternative to office visits can be a substantial risk to your practice. The following guidelines can minimize the potential liability:

- Inform patients in writing about when to seek telephone advice. Give examples of the types of complaints—for instance, minor headaches, cuts and bruises—that may be dealt with adequately over the phone. Also give examples of problems—such as shortness of breath and abdominal pain—that are likely to require a visit to the office or emergency room.
- Only physicians or qualified staff such as RNs, NPs, and PAs should provide telephone advice. Written protocols need to be prepared for the office staff; the protocols should include what questions to ask, recommended responses for minor problems, and which calls to refer immediately to a doctor or schedule for an office appointment.
- Give callers ample time to explain their problems. Avoid leading questions. Instead of asking, "Do you have any chest pain?" ask "Exactly where do you feel pain?"
- Be careful about prescribing by phone for new complaints. If your diagnosis is wrong, the medicine could be ineffective or even harmful.
- Document calls for advice in the medical chart, using the caller's own words whenever possible. If one of your staff members handles and documents calls, review the notes to make sure the adviser followed written guidelines and dispensed appropriate advice.

Best-Practice E-mail Guidelines

Although e-mail has all but replaced telephone conversations in some medical offices, many physicians remain reluctant to incorporate this communication tool into their practices. That's too bad, because e-mail can be an easy and effective way to communicate with patients. Still, certain basic guidelines should be followed:

- Be careful what you write. Always follow this rule of thumb: Never put in an e-mail what you wouldn't say in person.
- Get to the point. Don't ramble in your e-mails; be focused and concise. No one wants to sift through pages of text to get to the heart of a communication.
- Incorporate your contact information. Use the automatic signature function in your e-mail software to provide, at a minimum, your full name, your practice's name and your phone number in every message you send.
- Check your spelling and grammar before clicking "Send." Even in e-mails, misspelled words and bad grammar reflect poorly on you as a professional.
- Don't use all caps. Not only is it difficult to read e-mails typed using all capital letters, it's equivalent to screaming at the intended recipient.
- Use "emoticons" sparingly. The smiley faces and other graphical representations of emotions—called emoticons—that often pepper e-mails may be cute for friends, but they're rarely appropriate for professional communications.

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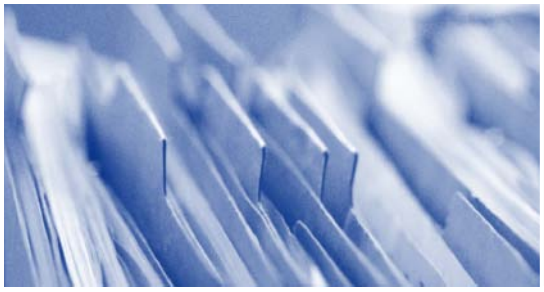

From the
RiskFile
Actual Closed SCPIE Claims Cases

Routine Steroid Treatment Leads To Catastrophic Permanent Injury

Risk Issues

- Lack of a treating physician's knowledge, teamwork among healthcare providers and thorough physical exams can turn routine steroid treatment for chronic back pain into catastrophic permanent injury and disability.

Summary

A 28-year-old female caregiver injured her back while attempting to move her elderly female client in May. The caregiver was diagnosed with left hip strain and lumbar disc bulge.

Although the patient received chiropractic manipulation and ultrasound treatments for six months, her pain did not subside. The primary care physician advised her to seek cortisone injections and referred her to a pain management specialist. During the informed consent process, the pain management physician did not mention the serious risks of Cushing's syndrome or avascular necrosis (AVN).

A course of four epidural injections was administered on a biweekly basis from October to December. The dosage consisted of 3cc's of Kenalog-40 corticosteroid (total 120 mg each).

After the initial treatment, the patient was seen three additional times for examination and followup by chiropractors at the pain center. However, no physician saw her at those visits despite her concerns about an "allergic reaction," indicated by a red and swollen face.

Between the third and fourth injections, the patient reported that she had gained 20 pounds. After the fourth injection, she had a large moon face and a huge hump on her back, and she began growing hair on her face, neck, chest, back and stomach. She was not seen again by the pain management specialist regarding these developments. As a result, diagnosis and intervening treatment were delayed for nearly a year.

Cushing's syndrome was ultimately diagnosed by other doctors. The following January, an MRI confirmed avascular necrosis of the hip.

It is anticipated that this young patient will continue to suffer from the partially resolved effects on her immune system and the unsightly appearance of Cushing's syndrome. Further, she will likely develop AVN in every major joint. She is currently a candidate for hip replacement surgery and will ultimately need knee replacements as well as shoulder and ankle surgeries.

Comments

Areas of risk exposure in this case include the following:

- Because the pain management physician considered the risk of developing Cushing's syndrome or AVN to be exceedingly low, he did not advise his patient of these serious risks during the informed consent discussion.
- Because the patient was seen by a chiropractor rather than the pain management physician at interval visits, important continuity of care was compromised. The patient reasonably expected

The goal of these analyses of actual closed SCPIE claims cases is to help minimize the medical malpractice liability of our insureds. In order to protect the privacy of the individuals involved, no names are used.

that all providers at the pain management facility would be adequately trained and would properly communicate with one another during her treatment.

Further, expert reviewers stated that during the course of treatment, each patient visit should have been a focused physical examination. According to the records, only range-of-motion exams were completed.

- Kenalog is manufactured in two doses: 10 mg/cc and 40 mg/cc. The pain management physician said that he was unaware of the strength of the Kenalog (40 mg/cc) kept in stock at his facility.

  All providers at a treatment facility should be aware of the dosages kept in supply and should be educated and alert to signs of emerging complications. Their observations should be communicated to all physicians and other healthcare providers.

- After this incident occurred, the pain management physician still believed that 120 mg doses were not dangerous. Experts reviewing the case indicated that the patient's problems were a recognized complication of powerful steroids such as Kenalog, and that the medical literature indicates a maximum recommended dose of 80 mg. Experts and the patient's endocrinologist concurred that giving large doses over a short period of time clearly resulted in the injuries claimed in this case.

  Any physician providing a pain management program must be educated regarding the appropriate doses, safe dosage intervals, appropriate monitoring and responsive treatment of developing symptoms.

- The steroid therapy was started more than six months following the injury. Expert reviews indicate that such therapy should be started no more than six-to-eight weeks after the injury. Even at an earlier point in time, therapy should be initiated using one trial dose only, with close monitoring to determine its efficacy.

Conclusion

This case illustrates the need for serious and thorough care by physicians endeavoring to provide chronic-pain relief. The physicians and other healthcare providers in this case violated several basic risk management guidelines for pain management.

The negligent treatment of this patient necessitated a settlement of nearly $1 million to compensate her for the tragic injuries that she will endure for the rest of her life. ■

Risk Watch: Effective Hospital Patient "Handoffs"

A study in the December issue of *Academic Medicine*, titled "Lost in Translation: Challenges and Opportunities in Physician-to-Physician Communication During Patient Handoffs," asks what happens when a hospital patient's physician goes off duty and another physician assumes responsibility for the patient.

The answer: Efficient and safe patient handoff often does not occur because physicians are inadequately trained in how to effectively communicate during these transfers.

According to the study's senior author, Richard M. Frankel PhD, poor communication in medical practice is one of the most common causes of medical errors. Among the study's findings: The safest method of transferring responsibility for a patient is face-to-face, during which the physician who is going off duty talks directly with the physician coming on duty.

Documentation: Not Just Paperwork —It's at the Heart of Patient Care

Of all the issues in risk management, none produce quite the same eye-rolling and sighing among physicians and medical staff as the topic of documentation.

Healthcare professionals who arrive at educational sessions and find documentation on the agenda tend to secretly—and sometimes not so secretly—wish they had called in sick.

That's unfortunate, because documentation is a cornerstone of medical care. In order to treat patients effectively, healthcare providers must hear their story, both from them and their family/support network. Then they must transmit that story to other involved parties. Good documentation is the way to communicate the story efficiently and accurately.

A thorough assessment of any patient begins with the patient's or family's description of what is going on. The plan of care—with its goals, strategies, time frame and measures of success—flows from this assessment.

> Lack of good documentation not only reflects less-than-optimal patient care, it is also a prime factor in liability loss.

For all members of the healthcare team to be able to do their part, they need to have access to the information generated through the assessment and in the plan of care.

Most physicians may be convinced that their documentation is comprehensive and complete, but closed-claims reviews across medical specialties demonstrate otherwise. They show that poor, incomplete documentation is present as a risk issue in at least 50% of medical malpractice cases.

Indeed, despite policies and procedures; checklists and tickler files; hospital, payer and government requirements; continuing education; and just plain nagging, medical records—which are the determining factor in 80% to 85% of all medmal lawsuits—can be woefully inadequate witnesses to the medical care provided.

In reviewing SCPIE's closed claims files, the following problems are frequently evident:

- Altered documentation
- Incomplete or missing documentation
- Allergy history not documented
- Lack of documentation of phone advice
- Missing progress notes and lab reports
- Illegible notes
- Incomplete informed consent
- Informed refusal not documented
- Patient education not documented.

Lack of good documentation not only reflects less-than-optimal patient care, it is also a prime factor in liability loss. In the absence of complete, consistent and comprehensible documentation, how can healthcare professionals possibly prove what they did, why they did it and what results they expected to achieve?

By focusing on documentation, are we caring more about paperwork than patient care? Not at all. Documentation—caring for the medical record—*is* patient care! ■

Bad documentation makes defense more difficult

Indemnity Paid	Allegations	Comments
$100,000	*Negligent prescribing, lack of monitoring and failure to obtain informed consent, resulting in damages to a 67-year-old male*	Had the physician fully documented the informed consent process regarding the patient's Prednisone therapy, as well as with whom the patient was to follow up for monitoring, the physician's ability to defend this suit would have been enhanced.
$450,000	*Delayed diagnosis of prostate cancer in a 47-year-old male*	There was no documentation that the physician discussed with the patient a PSA result of 7, recommended a urology consultation or gave advice regarding followup. Documentation of important unresolved clinical issues must be apparent to other physicians involved in managing a patient's condition.
$500,000	*Failure to diagnose and treat melanoma, resulting in wrongful death of a 38-year-old female*	The physician's entire documented record for this patient, who was seen over a period of several months, consisted of six scant entries. The physician said that because he was the only doctor treating the patient, the need for "excessive" documentation was unnecessary. Failure to adequately describe the appearance of the affected toenail or the nature of the infection prevented the oncology expert from staging the patient's cancer. Had there been good documentation in the medical record, the case would have been completely defensible from a causation point of view.
$225,000	*Wrongful death of a 42-year-old male resulting from a medication mixup*	The pharmacist misread the physician's prescription due to bad handwriting. The patient was given the wrong medication at eight times the recommended dosage.
$565,000	*Failure to diagnose a spinal cord tumor and to properly communicate the abnormal finding, resulting in damages to a 39-year-old male*	The radiologist did not document discussions with the chiropractor and the patient.
$233,000	*Wrongful death of a 48-year-old woman*	A non-English-speaking patient signed a Consent for Surgery form that was entirely in English. It was believed that the patient brought along her own interpreter, but none of the records contained a notation to that effect.

Not only is good documentation at the heart of patient care, it also can be pivotal in preventing medical malpractice litigation from taking place, or in enabling physicians to successfully defend themselves when lawsuits are filed. The table on the left summarizes six claims in which documentation—or lack thereof—played a key role.

SafePRACTICE

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- Never use abbreviations. When communicating with patients, abbreviations can lead to dangerous misunderstandings. Limit your use of abbreviations in e-mails to close friends or associates.
- Include a disclaimer. Communicate upfront your ground rules for e-mail exchanges. A standard disclaimer might read as follows: "Electronic mail is not secure, may not be read every day and should not be used for urgent or sensitive issues."
- Pick up the phone. If you cross e-mails with another party two or three times, or if there is an emotionally charged issue involved in what you want to communicate, stop e-mailing and place a phone call instead.

Guidelines developed by the eRisk Working Group for Healthcare urge physicians to offer e-mail "visits" only to existing patients whose medical history they are familiar with, rather than to patients they've never treated before. The guidelines—available online at http://www.medem.com/phy/phy_eriskguidelines.cfm—carry no formal legal authority but reflect a growing consensus about the safest way to practice online medicine.

Adopting good telephone and e-mail practices is vital to enhancing quality of care while simultaneously decreasing liability exposures that can occur. ■

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