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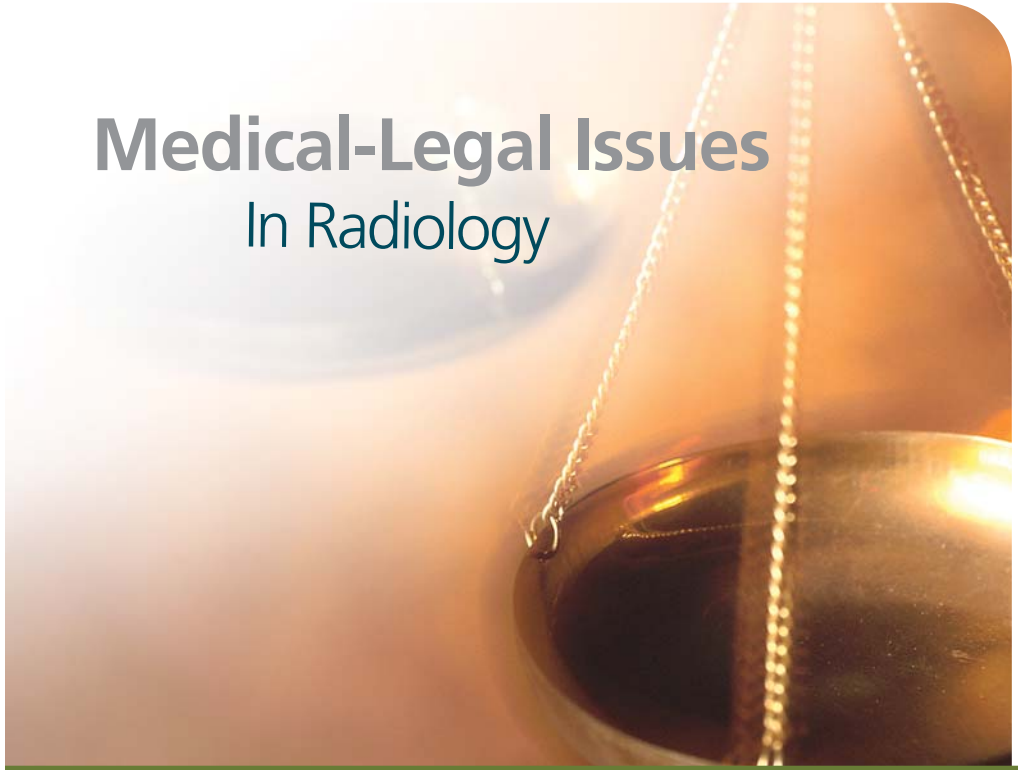
Medical-Legal Issues
In Radiology



Medical Liability
Contract Issues
Regulatory Issues

3rd Edition

ACR Medical-Legal Committee

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Foreword

Legal issues have become a significant part of the practicing radiologist's world. Most physicians receive little or no information about these issues in their training, and radiologists are no exception. This handbook is an attempt by the American College of Radiology to partially remedy this situation by providing the radiologist-in-training preparing to enter private or academic practice with basic information about the subject.

For many years, medical malpractice litigation was the only legal topic relevant to most medical practices. That is no longer the case. The managed care environment, competitive stresses among physicians, and hospitals and insurance companies mean contractual issues usually foreign to most physicians. The rapid increases in health care costs and new medical technologies, as well as increasing concerns about patient autonomy, have resulted in increased government regulation of physicians and the health care industry. As with contracting, regulatory issues often are foreign to most physicians.

Limitations on space, as well as on radiologists' time and interests, require that most of the topics addressed here to be dealt with only in an introductory fashion. We have attempted to avoid "legalese" wherever possible. For those interested in delving further into a subject, each section is followed by endnotes which include references and sources for further reading, many available on the Internet. Several Internet sites explaining legal citation are available, such as *http://wwwlib.murdoch.edu.au/guides/law/lawcite.html#cases.*

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Medical-Legal Committee
American College of Radiology

1. Medical Malpractice

BASIC CONCEPTS

Although it may seem otherwise to many physicians, the law does not provide a legal remedy for every wrong, real or imagined. In order to have a chance of success, a lawsuit must satisfy what are called the elements of a cause of action. In a medical malpractice case, a plaintiff must prove:

1) that the physician had a duty[1] to the plaintiff
2) that the physician breached that duty (i.e., his or her conduct fell below the "standard of care"
3) that this failure was the cause of the injury (causation)
4) that there are damages of a kind that the law will recompense[2]

As a practical matter, in medical malpractice cases the existence of a duty is not hard to establish, because the existence of a physician-patient relationship is usually not at issue. This issue may be a little more complicated in radiology cases where the radiologist reads under contract to a third party, as may be the case with B readers or employment physicals. The damages requirement usually is satisfied as well, since few attorneys will take a case unless there are damages (i.e., money). Therefore, the principal issues usually center on elements 2 and 3: Was the conduct within the standard of care? And, if not, did the alleged injury arise because of failure to meet that standard?

The standard of care is more a concept than a rule, since the standard applicable to a given case is decided each time on the facts of that case based upon expert testimony. Generally, the standard of care is met if the radiologist can demonstrate that he or she acted in a reasonably prudent manner under the circumstances. Published standards, such as those issued by specialty societies[3] have no legal standing other than serving as suggestions which a court, an expert or jury may or may not accept.

If the standard has been met, then there is no liability. This is the first and most effective line of defense, and attorneys for each party will attempt to find expert testimony favoring their side of this issue.

If the standard has not been met, the case is still defensible if the jury can be convinced that the patient's injury would have happened anyway (ie, failure to meet the standard was not the cause of the injury). For example, a cancer was so advanced that a delay in diagnosis made no difference in the outcome of the case, or that other injuries were so severe that the patient would not have survived anyway, despite a missed diagnosis by the defendant physician. It can be difficult to persuade a jury with such a "causation defense," but not impossible.

Expert testimony almost always plays the crucial role in deciding these questions and thus the outcome of the case. Given this fact, the defendant radiologist often has little control over the outcome once a suit is filed. However, there are things that the radiologist can do to improve the chances of a favorable outcome.

First, avoid discussing the case with colleagues. Such discussions are not privileged and their content may not be favorable to you. The plaintiff's attorney likely will ask with whom you have discussed the case.

> The most common error physicians make when sued is discussing the case with collegues.

Second, **never** attempt to alter medical records, such as your radiology report. Discovery of such an act, which is likely, will result in a very unfavorable settlement because a loss at trial is virtually certain, including the possibility of punitive damages.[4] Furthermore, alteration of medical records is a felony in some states raising the specter of a jail sentence, fine, or loss of medical license.[5]

Third, make it a habit to enter a note in the chart after every procedure you do, even though you intend to dictate a formal report. The note is a legal document contemporaneous with the event and written in your own hand, a fact that may have legal significance or even turn out to be crucial.[6]

Fourth, a willingness to talk honestly with patients is a good general rule, but only before the fact. Once a suit has been filed, limit your conversations on the subject to your attorney.

The legal requirements to be deemed an "expert" can be very broad, as can the requirements for admissibility of expert testimony.[7] The problem of "hired gun" experts and "junk science" expert testimony is familiar to defendants. In recent years, the federal courts have attempted to address this problem by defining criteria to be met before proffered expert testimony can be admitted, a lead followed by some but not all state courts. The ACR has incorporated some of these criteria in its Expert Witness Practice Guideline.[8]

ENDNOTES:

1 The legal concept of "duty" has a specific meaning. It arises out of a certain relationship between parties (such as the physician-patient relationship) without the necessity of a formal agreement or contract. It should not be confused with moral or religious definitions of the term.

2 The law does not compensate all injuries. For instance, mere hurt feelings, promises to marry, emotional upsets over injury to a distant relative, or exaggerations by salesmen are not usually compensable.

3 The American College of Radiology Practice Guidelines and Technical Standards are available online at http://www.acr.org/dyna/?doc=departments/stand_accred/standards/standards.htm.

4 "Punitive damages" are damages awarded not to compensate the plaintiff for injury but to punish the defendant for outrageous behavior; such damages usually are not available in medical malpractice cases. See *Moskovitz v. Mt. Sinai Med. Ctr.*, 69 Ohio St.3d 638, 635 N.E.2d 331 (Ohio 1994).

5 See, for example, Florida Statute 395.302, under which alteration of medical records can result in a 60 day jail sentence and loss of medical license. Nevada Revised Statute 630.3062 is similar. These are available online at www.findlaw.com.

6 California Evidence Code Sec. 225 and 1241.

7 The fundamental rule of evidence governing expert testimony is Federal Rule 702 which says: "…if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." The import of this rule in medical malpractice trials has been explained as follows: "the law defines an expert witness as basically one who possesses special knowledge or skill on a subject that is beyond common experience. Thus, the medical profession may consider that only a radiologist is 'expert' to interpret x-rays, but under the rules of evidence a physician who is a general practitioner is considered qualified as an expert witness on the subject of x-ray interpretation, because he has special knowledge and skill in the subject sufficiently beyond common experience to assist the trier of fact in reaching a determination of the disputed facts." (Jefferson BS. *California Evidence Benchbook*, 2nd ed, California Judges Association, Regents of the University of California 1972, 1975, 1978, 1982:985.)

8 The American College of Radiology Practice Guideline on the Expert Witness in Radiology, 2002 (Res. 43), effective 1/1/03. The full text is available online at www.acr.org/dyna/?doc=departments/stand_accred/standards/standards.html

INFORMED CONSENT

Overview

In modern medical practice, it is accepted that mentally competent adult patients have the right to determine whether or not they will receive a given medical treatment or service. This right is reflected in the doctrine of informed consent, which maintains that a patient has the right to know the risks and benefits of a medical service or treatment, as well as any alternatives, and to use that information as the basis for an informed decision on whether to accept that service or treatment.

Under the law, a successful informed consent action against a medical practitioner requires several elements: 1) a duty to the patient; 2) legally inadequate informed consent; and 3) patient injury resulting from that inadequate consent (the "causation" requirement). Since a radiologist or other practitioner providing a medical service to a patient has a duty to the patient under informed consent doctrine, this first element is rarely an issue. Rather, it the remaining 2 elements on which cases generally turn. The elements of informed consent are similar to those for malpractice, and as a practical matter allegations of failure to obtain adequate consent are usually part of a larger malpractice action, discussed further later in the text.

Standard for Informed Consent

State law determines what constitutes legally adequate consent as informed consent actions are generally adjudicated under state law. Not surprisingly, there are significant differences in this legal standard from state to state, though the various jurisdictions can be separated into 2 broad groups. Traditionally, states employed the "reasonable practitioner" standard, a test that asks what a reasonable practitioner in similar circumstances would have told his or her patient as part of the consent process. In practice, the standard was established by physicians testifying, as experts as to what information should have been related, a process that effectively kept delineation of the standard within the medical profession.

Reflecting the trend towards patients' rights, many states have moved to what is known as the "reasonable patient" standard. Contrary to the rea-

sonable practitioner standard, this newer test looks to a reasonable patient and what he or she would have wanted to know about a medical service prior to consenting to that service. While physicians may testify as to the actual risks, benefits, or alternatives to the service, it is the jury (or, if no jury is used, a judge) that determines what a reasonable patient would want to know. This is considered to be a more demanding standard, as it transfers the determination of what constitutes adequate consent away from practitioners and to the court.[1] What actually satisfies informed consent requirements under either standard depends heavily on the facts of a specific case, as the changing nature of medicine and the patient at issue means that there is usually not a previous court case to serve as a "precedent" to control a subsequent court's ruling. This fact-specific nature of informed consent actions often leaves radiologists and other practitioners with little solid guidance as to what patients should be told prior to studies or procedures, particularly regarding rare, but serious, complications.

> The war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a new code that is now accepted worldwide. Amongst [these are] the requirement of voluntary informed consent.
>
> – British Medical Journal, No. 7070, Vol. 313, p. 1448, 7 December 1996

Regardless of which standard is applied, it is crucial that any information supplied to the patient be in a form that the patient can understand, as failure to do so will result in a legally inadequate consent. For example, explaining a complex interventional procedure in medical terms to a patient with a high school education is arguably not providing that individual with meaningful information. Similarly, if the patient's primary language is not English, failure to supply information in that primary language may result in defective consent.[2]

Establishing Causation

Another key requirement for a successful informed consent action against a radiologist is the demonstration of causation, namely that a legally inadequate consent led directly to patient injury. In practice, this requires that a patient show that had consent been adequate, he or she would have either foregone the services that resulted in the injury, or chosen another study or procedure. The question of whether this requirement has been met is a question for the court.

The fact that some sort of patient injury is required for a successful informed consent action has implications beyond the doctrine of informed consent. Though this injury is not required to be physical (for example, giving a Jehovah's Witness blood products may not cause physical injury but could result in psychological trauma), it is in fact physical in the vast majority of cases. Where physical injury occurs, patients and their lawyers almost always will allege negligence in the provision of medical care; in other words, pursue a traditional tort malpractice action. Accordingly, it is relatively rare to see defective consent claims as a sole allegation against a radiologist or other provider. Typically, such informed consent action allegations are part of a broader action that includes a traditional malpractice claim.

Obtaining Legally Adequate Consent

The consent process with a mentally competent patient is rather straightforward. It involves explaining a medical service, its benefits and risks, as well as any alternatives, in a manner that the patient can understand and asking that patient whether he or she would like to proceed. Consent may be obtained in writing or verbally, though a written document with the patient's signature is useful as evidence of the consent. It is crucial to realize that the patient may revoke his or her consent at any time for any reason, verbally or in writing.

The informed consent process is more than a legal obligation, as it is often the patient's initial introduction to the radiology team and its services, and, accordingly, serves as an ideal opportunity to build a strong doctor-patient relationship. Care should be taken to address the patient's questions in an honest, truthful, and unrushed manner, in an atmosphere as free from coercion as possible. Accordingly, it is desirable to obtain consent for hospital inpatients in their room, or if outpatients are involved, in a room other that the procedure room, if possible. Similarly, consent obtained under coercive circumstances, such as obtaining consent for additional intervention during a procedure, may be invalid. There is strong evidence that physicians who succeeded in building relationships with their patients during the consent process are less likely to be the subject of

malpractice litigation than those physicians who performed rushed, impersonal consents.[3, 4]

A related issue is who on the medical team can obtain a patient's informed consent. There is a general agreement that the attending physician who is providing the service may obtain the patient's consent. Though some commentators argue that the attending physician must personally perform this function, most authorities maintain that the attending physician may delegate the consent process to someone else on the medical team, such as a resident or fellow, or perhaps an advanced practice nurse or physicians' assistant. If the consent process is delegated, the individual performing the consent becomes the "agent" of the attending physician, representing that attending physician to the patient. While the attending physician may delegate the consent process, he or she remains liable for the legal adequacy of the consent provided, as well as the reasonable actions of the agent.[5] For their own part, radiology residents who are asked to obtain informed consent should do so conscientiously, honestly representing their role in the team and service provided, and directing any questions they cannot personally answer to individuals who can. In practice, this means that a resident or fellow who performs a consent process as instructed by the attending radiologist, or as would be considered reasonable under the circumstances, would not be liable for an inadequate consent. However, if that same resident or fellow explicitly disregarded the instructions of the attending radiologist, or in some other way exceeded the authority delegated by that radiologist, that trainee could be liable for the inadequate consent, not only to the patient, but also to the attending.

Informed Consent and the Legally Incompetent Patient

Inability of an adult patient to consent due to mental incompetence or an inability to communicate raises questions of who may consent for that patient. If the period of incompetence or inability to communicate is likely to be temporary, such as is the case where the patient has been administered psychotropic medications or temporarily paralyzed and intubated, it is prudent to delay or forgo elective procedures for which consent is necessary until the patient is once again able to give consent. Should the inability to give informed consent be indefinite, or a non-elective procedure be at issue, consent should be sought from a surrogate decision maker.

There is a definite hierarchy among those who may make medical decisions for a patient unable to consent for themselves. Where allowed by the state law, medical surrogate decision makers are at the top of this hierarchy. These individuals are designated by the patient in a formal legal process during a period of competence to make that patient's medical decisions, should that patient subsequently become incompetent. The judgment of these surrogates trumps all other individuals, even the patient's close family. Second only to medical surrogates are individuals legally designated to make general decisions for the patient during a period of incompetency, such as a legal guardian. Permitted in some form in all US jurisdictions, those holding general decision-making powers generally hold legal sway above any relative. With either type of legally designated surrogate, it is important to recognize that patients often designate such surrogates where they are concerned that their own wishes regarding medical care will not be respected by those closest to them.

Following those established by formal legal processes, the family of the patient becomes the surrogate decision maker. Within a family, there is a consent hierarchy as well. Spouses' decisions are considered the most important under this hierarchy, followed by immediate relatives such as parents, children, and siblings. If no close relatives are available, a provider can turn to a more distant relative for informed consent.

While the patient's wishes regarding a surrogate decision-maker are relatively clear with legally designated individuals, disagreements often arise when decisions are left to the patient's family. It is not at all uncommon for members of the patient's family to disagree on an incompetent patient's care, often in a manner that leaves radiologists and other health care providers confused and uncertain how to proceed. In such cases, it is usually best to seek consensus among family members, or if significant disagreements persist, to involve the institution's legal resources to effect an acceptable solution. Importantly, when radiologists or other providers move forward with a service or treatment in the face of unresolved family disputes, lawsuits frequently result, particularly should there be a complication or untoward outcome.

Individuals under 18 years of age are considered minors, and with some exceptions, are legally incapable of giving consent. For non-

emergent, general medical issues, a parent or legal guardian must give consent. However, most states have provisions allowing minors to consent to care provided in the context of reproductive health matters, such as pregnancy and abortion-related services, birth control (though sterilization is frequently treated differently), and treatment of sexually-transmitted diseases. Minors in their teens may also seek legal "emancipation" from their parents, a legal process where they are essentially declared independent and free to make their own legal decisions, including medical care.

Where surrogate decision makers are involved, it is ideal to obtain face-to-face consent. However, in many cases, such decision makers are not physically available and consent must be obtained by telephone. While telephone consents are legally valid, several considerations unique to such consents should be observed. Initially, after the professional asking for consent has obtained it, the verbal consent should be documented by a witness who also personally speaks to the surrogate decision maker. This ensures that all questions have been answered and that the decision-maker would like to proceed. Ideally, the witness should not be directly involved in the patient's study or procedure. Care should be taken to document a telephone verbal consent, including the decision maker's name and the telephone number at which they were reached, on a written instrument signed by both the provider obtaining the consent and the witness.

Duration of Consent

Whether obtained from the patient or a surrogate decision maker, informed consent does not last indefinitely. This duration becomes an issue when consent is obtained, and for any number of reasons, the procedure or therapy is not immediately performed. Though often subject to specific institutional policies, a good rule of thumb is that consent is valid for 24 hours after it is obtained. If more than 24 hours has passed and the procedure in question is still being considered, it is best to re-execute the consent. This process need not involve the entire consent process if the original consent was recent and the patient or surrogate decision maker does not require more information. In such cases, merely asking whether the procedure is still desired and having the original consent document initialed and dated by that patient or decision maker is enough to proceed. However, if more than 2 or 3 days have elapsed since the original consent, it is prudent to obtain formal reconsent.

Implied Consent

While it is always desirable to obtain informed consent from a patient, or where the patient is incapable of giving consent, from a surrogate decision maker, there are limited instances where informed consent may be implied. Generally, such circumstance exists only in life-threatening situations, where the patient is unable to give consent and no surrogate decision maker can be identified or contacted in a timely fashion. In practice, such emergencies are limited to the trauma or critical care setting, or where an immediately life-threatening complication develops in the course of an elective medical procedure. Under these circumstances, the law assumes that, absent any qualifying patient instructions that should reasonably be known to the health care team (such as a standing refusal for blood transfusions on the part of Jehovah's Witnesses), the patient would desire any and all reasonable treatment to be undertaken. In many instances, there are institutional policies that dictate how such emergencies should be documented. Regardless, it is always desirable to have a second physician document that an emergency situation exists and concur in performing the anticipated procedure, and document this second opinion, before proceeding with a study or therapy under implied performed consent.

Consent with Clinical Trials

Informed consent involving an experiment procedure or medical product is a special case, where specific institutional and federal regulations apply. Generally, consent in such circumstances involves detailed informational informed consent documents that have been approved by the institution's institutional review board (IRB) and, in the case of drugs or significant risk investigational medical devices, the US Food and Drug Administration (FDA). As with traditional consent, experimental therapy or products may be used in limited emergency circumstances without obtaining consent, though such use will almost always trigger IRB or FDA scrutiny. In any event, such emergency use should be extremely limited and occur only where no other option is available.[6]

Summing Up

As a doctrine, informed consent represents a refreshingly simple concept, namely that competent patients have the right to determine the course of their medical care. It also represents a true opportunity to introduce yourself and your service to the patient, and to build a productive doctor-patient relationship. When accomplished in a conscientious and thoughtful manner, with consideration paid to the legal requirements, effective consent can serve to mitigate a radiologist's legal exposure.

ENDNOTES:

1 As of September 2003, the physician-oriented standard is applied in Alabama, Arizona, Arkansas, Colorado, Delaware, Florida, Illinois, Idaho, Kansas, Maine, Michigan, Missouri, Montana, Nebraska, Nevada, New Hampshire, North Carolina, South Carolina, Tennessee, Virginia, and Wyoming. The patient-oriented standard is applied in Alaska, California, Connecticut, Hawaii, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Washington, West Virginia, Wisconsin, and the District of Columbia. An interesting discussion of informed consent is found in Bulen Jr JA, *"Complementary and Alternative Medicine: Ethical and Legal Aspects of Informed Consent to Treatment",* Journal of Legal Medicine, 24:331–358, Taylor & Francis, 2003.

2 Title VII of the U.S. Civil Rights Act requires health care facilities, including most physician offices, to provide a means of communication for patients with limited English proficiency, and the Joint Commission on Accreditation of Healthcare Organizations and the American Hospital Association have made this accommodation a condition of accreditation. In the research setting, the Department of Health and Human Services (DHHS) regulations (45 CFR 46.116 and 45 CFR 46.117) and FDA regulations (21 CFR 50.25 and 21 CFR 50.27) require that informed consent information be presented in language understandable to the subject, and in most situations, that informed consent be documented in writing. A brief practical primer on dealing with this situation is Higginbotham, Elizabeth, "How to overcome a language barrier", RNWeb® Archive Oct 1, 2003 at http://www.rnweb.com/be_core/content/journals/r/data/2003/1001/lstranslator.html.

3 The degree to which physician communication skills with patients impact malpractice exposure may depend to some degree on the doctor's specialty. Evidence that this factor is more important for primary care physicians than surgeons can be found in Levinson W, Roter DL, Mullooly JP, Dull VT, and Frankel VT, *"Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons"* JAMA Vol. 277, No. 7, Feb 19, 1997.

4 In general, a physician is not required to reveal personal information as part of obtaining informed consent. Of course, this does not extend to misrepresentation of one's qualifications or concealing the existence of a direct financial conflict of interest. See *Moore v. Regents of the University of California* 793 P.2d 479 (Cal 1990), involving a physician's financial interest in development of a cell line from a patient's spleen.

5 The authority of an agent to act on behalf of a principal can be either "express" or "apparent." Express authority exists where the principal has given explicit authority to the agent to act on his or her behalf. Apparent authority arises out of a third party's reasonable belief that the agent has authority to act for the principal. Such a belief could be reasonable if 1) a principal creates the appearance of an agency relationship, (2) a third party relies on that representation, and (3) the third party changes position in reliance on that representation. It is possible, therefore, for a principal to be held liable for the actions of his or her agent even in the absence of express instruction or permission. Hospitals have been held liable for the actions of non-employee, hospital-based physicians under this legal theory. For a recent case involving a radiologist, see *Roessler v. Novak*, No. 2D02-1670 (Fla. Dist. Ct. App. Nov 7, 2003).

6 An extensive discussion of problems in this area is found in Tector Leslie M. and Allen Mary Ellen, *"The Johns Hopkins Experience: A Blueprint for Clinical Research Compliance,"* Group Practice Journal, Sept 2001.

NATIONAL PRACTITIONER DATA BANK

The Data Bank (established on Sept 1, 1990) is a federal repository of reports of medical malpractice settlements, judgments, and other actions entered against individual physicians.[1] In that circumstance, the malpractice insurance carrier is required to file such a report with the Bank. Many states require a similar report to their medical board for payments over a certain figure (for example, $30,000 in California).[2] There is no such *de minimis*[3] exception for the federal Data Bank; a payment of just $1 or even one penny would have to be reported. Hospitals are required to make an inquiry at the Bank whenever a physician applies for privileges. Other entities that conduct peer review are eligible (though not required) to make inquiries as well[4]; as a practical matter, they almost always do. As of Dec 31, 2001, the Bank contained 291,520 reports on 178,475 practitioners, mostly physicians.[5] The reports are not freely accessible to lawyers or the public, a fact that various interest groups have been trying to overturn.

> There are about 750,000 physicians in the U.S. About 23% of them have been reported to the Data Bank. Of these, two thirds have a single report.
>
> – NPDB Annual Report, 2001

You have a right to view the report by querying the Data Bank. You can challenge the content of a report when it is filed by requesting that the reporting entity change it. If the entity refuses to do so, you may submit to the Data Bank a statement, or dispute its accuracy through the United States Department of Health and Human Services. When the Data Bank receives a properly completed dispute from you, it will notify all parties that have previously queried the Data Bank and received the report that you have disputed the report.

The Data Bank only requires reports regarding individual physicians. Consequently, if an organization (such as an academic medical center or large medical group) is the named defendant, no report is required.[6] Further, only payments by third parties (ie, usually insurance companies) must be reported. If a physician were to pay the settlement or judgment personally, no report would be required.[7] Proposals have been made to close these "loopholes."

Endnotes

1 The National Practitioner Data Bank was established by Congress as part of the Health Care Quality Improvement Act of 1986 (42 U.S.C. § 11101, et seq.)

2 California Business and Professions Code Sections 801, 801.1, 803(b) and 803.2

3 A legal term meaning "minimal amounts or offenses."

4 Health care entities such as HMOs, preferred provider organizations, and group practices may query if they provide both health care services and follow a formal peer review process to "further quality health care." This includes organizations that both employ and contract with providers, such as nursing homes, rehabilitation centers, hospices, renal dialysis centers, and free standing ambulatory care and surgical centers. Insurance companies are generally excluded. (*National Practitioner Data Bank Annual Report 2001*, available online at http://www.npdb-hipdb.com/pubs/stats/2001%20NPDB%20Annual%20Report.pdf at page 26). This report contains detailed information about the Data Bank, including the marked variability in the size of payments between different states (for example, the 2001 median payment in Nevada was $225,000; next door in California it was $65,000; ibid, Table 9).

5 Ibid, p. iv

6 Ibid, p. 15

7 Ibid, p. 3, footnote 7

LIABILITY IMPLICATIONS OF MEDICAL GROUP STRUCTURE

A medical group may be organized as a partnership or a corporation.[1] The two forms of organization differ significantly as to rules of governance, dissolution, and liability exposure of their members.

Radiologists in an incorporated group are liable for their own malpractice (generally covered by their individual malpractice insurance policies), but not for the actions of their fellow shareholders unless the corporation has some uninsured derivative liability (the concept of derivative liability is discussed further later in the text). In that case, the liability of the other radiologists extends only to the extent of the value of their stock (their other personal assets are not at risk). Therefore, it is important for the medical corporation to insure each of its members individually as well as the corporation as a separate entity.

In a situation where insurance coverage may be inadequate, plaintiffs may try to get around the corporate structure protections and attack the shareholders' personal assets (beyond their share value), which, if successful, is called "piercing the corporate veil." Success in such an effort requires showing that the medical group is a corporation in name, but not in fact; that is, it has not adhered to the strict requirements of corporate governance and structure.[2] If the "corporate veil" is pierced successfully, the organization will probably be held to be a partnership in fact, if not in name.

"S" corporation status may have tax advantages for the radiologist. "S" corporations can have no more than 75 shareholders.

The members of a partnership are personally, jointly, and severally liable[3] for the uninsured or incompletely indemnified financial obligations of the partnership to the extent of their assets, but not their stock (there is no stock in a partnership).

ENDNOTES:

1 A hybrid form of both, called a "limited liability company," exists in many states, and will not be further discussed here.

2 Among the requirements for corporate status are the filing of articles of incorporation with the state, payment of annual fees to the state, drafting of corporate bylaws, the need for meetings of shareholders and directors at specific intervals, keeping of a minute book, and, in the case of a medical corporation, ensuring that only licensed physicians are shareholders. "Piercing the corporate veil" requires a showing of such things as incomplete or improper compliance with these procedural requirements, commingling of personal and corporate assets (the "alter ego" doctrine), or maintaining inadequate insurance for foreseeable liabilities. "Piercing the veil" is harder in some states than others.

3 "Joint and Several Liability" means that all liable parties are equally liable. That is, if one party is unable to pay, the others must make up the difference. One of the principal advantages of a corporate as opposed to the partnership structure is that parties can avoid this possibility.

THE "CURBSIDE CONSULT"

Informal consultation with clinicians is an integral part of most radiologists' practices. It probably cannot and even should not be avoided. Nevertheless, the radiologist should be aware that such conversations (as opposed to the formal report) carry a legal risk. Liability for the radiologist in this situation arises only if he or she is shown to have a duty (element 1, above) to the patient being discussed. No duty exists if there is no doctor-patient relationship. The evidence needed to establish such a relationship can be minimal; a formal radiology report may not be necessary.[1] Courts tend to find a doctor-patient relationship if the radiologist provides information that leads to treatment decisions. In such situations, the radiologist's liability will be based on what he or she is alleged to have said, since there usually is either no written record of the conversation or only the clinician's note. You can help reduce potential liability by keeping your own notes regarding such conversations, such as "1/1/04: Discussed head trauma case with Dr. Jones. Explained strengths of CT v. MR." Several courts have ruled that a diagnostic radiologist is liable in such circumstances for failing to communicate with clinicians about unexpected significant findings.[2]

ENDNOTE:

1 The notion that very little is needed to establish a doctor patient relationship is well established. For instance, see *Vita v. Dolan*, 155 N.W. 1077 (Minn 1916), which held that a doctor-patient relationship can be established even if the patient does not know the physician, engage his services, or pay for them.

2 See, eg, *Corteau v. Dodd*, 773 SW2d 436 (Ark 1989).

HMO MEDICAL MALPRACTICE LIABILITY

Health care in the United States has generally been paid for by third parties; that is, insurance companies or the government (Medicare and Medicaid). Traditionally, these payers exercised little, if any, control over what treatment was administered or where the patient went for care, a circumstance that was thought by many to encourage waste and contribute to the rising cost of health care. This belief gave rise to the health maintenance organization (HMO), which not only pays for the care but exerts varying degrees of control over what care is given and by whom. Under the law, the ability to control another often gives rise to at least potential liability, under a legal concept called "derivative liability."

> As of May 2000, 42 class action lawsuits were pending against managed care plans.
>
> – Saccocio L, Wilber K; presented at the 11th annual Managed Care Law Conference, Kiawah Island, SC, April 30-May 2, 2000.

Derivative liability arises not out of one's own actions, but out of the actions (or omissions) of another party over whom one has control or the right to control. The classic example is the employment relationship: the radiologist (employer) is responsible for the acts of his or her employees, such as technologists, nurses, and clerks.[1] Under this line of reasoning, many attempts have been made to hold HMO's at least partially liable for medical mishaps. These efforts were significantly hampered by 2 factors. One factor is that HMO contracts with physicians always contain a clause explicitly stating that the physician is an independent contractor, not an employee. This makes it more difficult to prove a degree of control sufficient to establish derivative liability. A second is the Employee Retirement Income Security Act of l974, better known as ERISA.[2] This federal law governs employer-sponsored health plans (which most HMO plans are), pre-empts state law,[3] and spells out the legal remedies available to a plan participant (ie, patient) in a dispute with the health plan. Under this law, these remedies are very limited, in essence immunizing HMOs from money damages for tort[4] and leaving the involved physicians solely responsible. The injustice of this scheme in many situations has led to considerable softening of this rule by US Supreme Court and federal court decisions, with the result being that HMOs have found themselves more exposed to potential malpractice-related liability.[5]

ENDNOTES:

1 Derivative liability arising in the employment context is called "respondeat superior." Another form of derivative liability arises where the party to whom the liability attaches has behaved in such a way that another person could reasonably believe that he or she has assumed responsibility for another's actions or should be held responsible for those actions. This is called "ostensible agency," "apparent agency," or "holding out."

2 Employee Retirement Income Security Act of 1974 (ERISA), 88 Stat. 832, as amended, 29 U.S.C. §§ 1001 *et seq.* (1994 ed. and Supp. III).

3 "Pre-emption" refers to the legal doctrine under which federal law supercedes, and in some cases voids, or replaces, state law dealing with the same subject.

4 A tort is a civil wrong as opposed to a criminal act or breach of contract. Medical malpractice is a tort.

5 The leading case is *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350, l995, holding that claims of medical negligence (as opposed to disputes about the extent of coverage) against health maintenance organizations are not preempted by ERISA. But the US Supreme Court has not been willing to extend HMO liability too far; see *Pegram v. Herdrich*, 530 U.S. 211; 120 S. Ct. 2143(2000), which held that HMOs do not have a fiduciary responsibility to their customers when rendering mixed eligibility and treatment decisions.

2. Contract Issues

EMPLOYMENT CONTRACTS

Income from professional services is often the single greatest source of lifetime earnings for radiologists. Accordingly, the contracts that govern the employment relationship between a radiologist and his or her practice are often the most important financial documents he or she will ever sign. Given that it is much easier to alter the terms of professional employment before a contract is finalized, it is vital for the radiology resident to identify and address key contract issues before any contract is signed.

A contract is a legal document that binds the parties to the agreement to certain, specifically enumerated obligations. At a basic level, it is important to realize that the contract, unless specifically provided for, contains all aspects of the employment agreement.[1] From a strictly legal perspective, this means that if something is not provided for in the contract, it does not exist. Furthermore, as the contract forms a legal obligation, a radiologist is bound to its terms and cannot alter them, unless the other party to the agreement agrees to the change.[2]

Form of Employment

The actual employment relationship between a radiologist and his or her practice differs considerably from practice to practice and is heavily influenced by the radiologist's experience. Those completing their training are typically considered "employees" in their initial contract, meaning that they provide professional services and, in turn, receive compensation. An employee has no ownership interest in the practice, as would occur when a radiologist is made a partner or offered the opportunity to become part of a professional corporation, a transition usually predicated on successful performance as an employee. The basic terms of an initial employment contract as they apply to an employee are discussed in the following sections.

Term of Agreement

A basic contract provision is the length or term of the employment agreement. Most radiology contracts for those completing their training have terms of 1–3 years, usually with provisions to renew or modify the relationship, such as grant partnership,[3] at the end of the period. It is standard practice for employers to have a right of "for cause" dismissal, which allows for termination of the agreement, generally when certain enumerated events occur. These typically include loss of hospital privileges or medical licensure, failure to obtain board certification, removal from Medicare or other insurance programs, criminal convictions, and similar events that impact the ability of a radiologist to provide clinical services or objectively raise serious questions about ethics and character. It is also standard for a radiologist to be granted the right to voluntarily leave a practice with reasonable advance notice (generally 60-90 days), or to void the contract immediately on the agreement of both the radiologist and the practice. If a contract does not contain a voluntary termination provision, it is important to realize that the radiologist is legally bound to the practice, unless the employer agrees to termination. While a radiologist in such circumstances can always physically leave the practice, he or she may be liable for damages, such as the cost of hiring a replacement and lost practice revenue that may result from the departure. However, most physician employment contract litigation centers around alleged violations of covenants not to compete, discussed later in the text.

Compensation

A key issue in any contract is the compensation a radiologist receives for his or her services. Starting salaries for those completing their training varies, driven by such considerations as practice type (academic versus private practice), the local market for radiological services, radiologist training (ie, has the radiologist completed a fellowship), and the length of time until a new hire is offered an ownership interest such as partnership. In some practice environments, bonuses, the amounts of which are usually not defined in the contract, form a substantial portion of the compensation package.

Whatever compensation is provided for, the contract should be explicit as to when payment is made. In addition, most contracts typically feature provisions outlining how any outstanding compensation is to be paid, should the employment relationship be terminated.

> BEWARE OF THE CONTRACT THAT DOES NOT MENTION CALL. Too many residents have been seduced by the siren-like whirr of a bottomless ATM spewing cash, only to get closer and find that the sound was, in fact, the all too familiar chirp of a beeper.
>
> – Wall, JD, "A Physician's First Real Employment Contract," online at Scutwork.com

Working Conditions

An important consideration for radiologists beginning their professional lives is the day-to-day working conditions, including the practice mix of subspecialty to general service, and call obligations. Traditionally, such conditions were often vague in many radiology contracts, leaving the practice with considerable flexibility in how to schedule the radiologist's professional time. With the move towards subspecialty practice, provisions providing for a certain percentage of subspecialty practice are becoming more frequent, though it is still quite rare for call obligations to be explicitly included within the contract. If a certain amount of subspecialty practice is desired, it is always advisable to have an explicit provision for such practice specified in a contract.

Vacation and conference time typically is specifically enumerated in contracts. The amount of such time is highly variable, often less in academic environments than private practice settings. However, academic practices often are quite flexible with vacation and conference time, while private practices carefully monitor such time, often requiring commitment far in advance and giving radiologists with seniority first choice. Regardless of the practice setting, it is highly advisable to have vacation and meeting time included in any contract.[4]

A related issue is who will pay for continuing medical education (CME) expenses, even when such time is explicitly defined in the contract. It is fairly common for practices to either provide a fixed, annual sum for such expenses, or reimbursement for "reasonable" expenses, often with prior approval. Regardless of how reimbursement of CME expenses is structured, it is best to have provisions describing those policies within the employment contract.

Malpractice Insurance

Most contracts for radiology services explicitly provide for malpractice insurance coverage, though the level of coverage detail is variable. If malpractice insurance is not mentioned in the contract, there is the distinct possibility that the cost is not paid by the practice, a strategy that has been used to make starting salaries appear artificially high. Should malpractice insurance be provided, it is important that the radiologist determine the type of coverage offered.

Malpractice insurance comes in 2 distinct forms, "occurrence" and "claims-made," with important financial implications for the radiologist. Occurrence policies provide coverage for any legal action that may result from an incident that occurred during the period when the policy was in effect, regardless of when that action is brought. For example, if an occurrence policy is in effect in the calendar year 2001 and a radiologist misses a small, potentially curable lung cancer during that year, that 2001 policy would provide coverage for a subsequent lawsuit related to that missed diagnosis, regardless of when the suit was brought.

Claims-made policies are quite different and provide coverage only for legal actions brought during the time period in which they are in effect. Returning to the example of a lung lesion missed in 2001, if a lawsuit was brought in 2003, coverage would depend on having a claims-made policy in force when the action was actually brought, as the claims-made policy covering 2001 would have expired. Given the volatility of the medical liability insurance market in recent years and the fact that it is much easier for insurance companies to determine radiologist malpractice exposure on a year-to-year basis, claims-made policies now constitute the majority of policies written in the United States.

If a practice provides claims-made malpractice coverage, there are important considerations for the radiologist should he or she wish to move to another practice. Specifically, claims-made policies generally expire when a radiologist leaves a group and subsequent claims made policies at a new practice generally exclude coverage for actions stemming from incidents that occurred in prior practice. This means that insurance must be purchased to cover claims stemming from incidents in a prior practice that may be brought in the future, commonly referred to as "tail" coverage.[5] Typically, radiology practices with claims made policies do not provide for tail coverage, at least in the first 2 to 3 years at a practice. Such coverage can cost tens of thousands of dollars, generating a substantial, often unanticipated, expense should a radiologist decide to leave a practice.[6] Therefore, radiologists should try to negotiate for tail coverage as part of their employment contract or partnership agreement.

Benefits

Most radiology contracts provide for health and life insurance coverage, though the documents frequently only allude to benefits provided by the group, and not to specific policy provisions. It is always prudent to carefully review the practice's current benefits package to determine its suitability for personal needs, bearing in mind that packages outside of the contract can generally be altered at any time.

Disability and dental insurance may or may not be provided for in a radiology contract. While dental insurance may or may not be important to individual radiologists, disability insurance, which provides compensation should a radiologist no longer be able to practice, is considered crucial for any individual whose livelihood depends on his or her professional activities. Given the rising cost of physician disability insurance and the purchasing advantage that may be gained by obtaining such coverage through an employer, it is prudent to explore whether a practice is willing to provide disability insurance as part of the employment package.

Reference to retirement plans also is included in many radiology contracts, though as is the case with health and life insurance, specifics are often not part of the contract. It is always best to fully explore what type of plan a practice has in place, such as provisions for a 401(k) plan and practice contributions to any retirement plan. Even in large organizations, it is very rare to see "defined benefit" plans, where the benefits upon retirement are guaranteed. Rather, most employer contributions take the form of "defined contribution" plans, where the practice will either contribute a certain amount to the employee's retirement accounts (usually based on salary, up to a limit provided for by law) or match an employee's own contributions to such an account.[7]

Partnership and Other Ownership Interests

The ultimate goal of a resident or fellow signing their initial employment contract often is to become a full member of a practice and assume an ownership interest in that practice, referred to as gaining "partnership." In reality, true partnerships are only one of a variety of ownership mechanisms that exist, the implications of which are often specific to the state where the practice is located, and in any event, are beyond the scope of a basic overview.

The time required to become a full member of any practice, as with compensation, is variable. Generally, however, the increasingly tight market for quality radiologists has forced this time to 1–3 years, with most practices requiring at least 2 years. Shorter timeframes are often seen with more rural practices, while urban practices in desirable cities tend to have longer tracks.

A key consideration with an ownership interest is whether a "buy-in" is required, a payment that secures a share of the assets held by the practice, and by implication, the revenue generated by those assets. Whether a buy-in is required and the ultimate amount of that buy-in depends on the form of the practice and its assets. If the practice is hospital-based and does not own any equipment or significant infrastructure, there is often a low buy-in, if any. However, where a practice owns its own equipment (particularly CT, MRI, or angiography units) or infrastructure (such as an office building or billing operation), buy-ins may be considerable, often amounting to hundreds of thousands of dollars.[8]

A radiologist securing an initial employment contract and eventually seeking an ownership interest should determine whether a buy-in exists and how much recent buy-ins have cost. If a buy-in is involved, an effort should be made to secure an agreement as to the amount of the buy-in should he or she successfully complete their period as an employee, with common practices including fixing a sum beforehand, or linking the buy-in to an objective measure of the practice's worth, such as a percentage of the accounts receivable. Simply put, the offer of an ownership interest becomes worthless if the buy-in is set at a level that the radiologist cannot afford. Similarly, where a significant buy-in is anticipated, the radiologist should fully explore what mechanisms exist to recoup those funds, should he or she eventually leave the practice.[9]

Covenants Not to Compete

Radiologists, as consultant physicians, often build strong bonds with referring physicians. These bonds are at the heart of a practice's overall success, but can become problematic from the practice's perspective should the radiologist elect to leave, particularly if the radiologist remains in the same community and competes for the same referring physicians. Covenants not to compete are the legal answer to this risk.

Covenants not to compete are present in the vast majority of employment contracts with private radiology groups, though they are unusual in contracts with academic or government (such as the Veteran's Administration) practices. Typically, these provisions specify a number of years before the departing radiologist can practice in certain practice environments (specific hospitals or clinics), or within a certain geographic distance of a particular hospital or locality. Actual provisions vary widely, but tend to be more restrictive in rural or semi-rural areas, or in any practice setting where there is limited competition.

In court, covenants not to compete are generally upheld where they are found to be "reasonable," a definition that varies widely with the facts of a given situation.[10] In practice, provisions with short duration (1–2 years) and restricted applicability (with 5–10 miles in semi-rural setting, for example) would probably be enforceable. Regardless, any radiologist signing his or her initial contract should pay careful attention to the covenant not to compete, and assume that the practice will make every effort to enforce its provisions.[11]

Other Considerations

A radiologist negotiating his or her contract is frequently in the strongest bargaining position with their employer that they will enjoy in the early part of the employment relationship. Once the contract is signed, employer willingness to provide additional concessions typically is limited. For this reason, a radiologist should carefully consider what he or she feels is necessary to provide an effective and enjoyable working environment, and make every effort to include these items in the contract.

For example, many radiologists would like a private office or use of an administrative assistant. Those in interventional practice often require a paraprofessional, such as a nurse practitioner or physician assistant, to provide efficient service, or may feel special equipment is necessary. If travel is involved between practice locations, a car allowance may not be unreasonable. These and other conditions should be carefully considered before a contract is finalized.

Enforcing Contract Provisions

A radiologist signing an employment contract also should be aware of what may occur if its provisions are violated. Importantly, enforcement of contract provisions by the courts is not automatic. If either the employer or employee feels that the other party is not abiding by the contract's provisions, that party must obtain a legal determination that the contract was violated, as well as the level of damages that accrued to that violation.

Traditionally, determination by a court was necessary to establish contract violation and damages. However, modern contracts may have provisions that dramatically alter this mechanism. It is not usual for a radiology contract to contain a "liquidated damages" clause, a provision that explicitly defines what monetary damages are owed, generally to the employer, should the contract be violated. Such provisions may also provide for the offending party to cease a specific practice, such as providing radiology services in violation of a covenant not to compete, or compel the employee to pay the employer's legal expenses. The existence of such a clause means that a court need only determine that the contract was broken before damages are assigned.[12]

In many employment settings, contracts contain arbitration provisions, clauses that compel employer and employee to submit to binding arbitration should a dispute arise. Commonly, this arbitration is in lieu of a court proceeding, with limited or no appeal and sometimes at a high cost. While presently uncommon in radiology contracts,[13] it would not be surprising to see such alternative dispute mechanisms become more common as radiology groups continue to grow and become increasingly sophisticated.

Regardless of how a contract is written, there are several underlying factors to consider. Initially, it is unusual for a court or arbitrator to compel a radiologist or other employee to work in an environment against his or her will, or to force the closure of a radiology practice, as might arise with a covenant not to compete. Similarly, while it is not as unusual for a court to compel a practice to keep a provider on staff, it is rare that a radiologist or other provider would wish to work for a group with which he or she had a legal dispute. This means that the overwhelming majority of contract disputes revolve around monetary damages. It is also the case that most potential contract disputes are not subjected to a formal legal process, and instead are settled in some way through negotiation between the radiologist and his or her practice.

Summing Up

Contracts represent a major financial decision for the radiologist completing training and involve a variety of complex legal considerations. Given the complexity and financial implications, it is always advisable to seek an attorney knowledgeable in health provider contracts in the jurisdiction in question to have that attorney carefully review the contract for potential issues. Still, despite its black-letter requirements, a contract is only as sound as the people who make it, particularly given the difficulty of compelling either the radiologist or employer to maintain an amicable professional relationship. Accordingly, radiologists should ask themselves whether they trust a potential employer and realistically could see themselves working with that group before even considering the terms of a contract.[14]

ENDNOTES:

1 Almost all contracts contain an "integration" or "merger" clause to prevent admission of evidence about "what was really intended" if a dispute arises after the contract is entered into. A typical integration clause reads: "Integration Clause: This agreement is the entire and sole agreement of the parties hereto with respect to its subject matter. It may be modified or amended only by a written instrument executed by the parties hereto. There have been no representations, warranties, or promises outside of this agreement. This agreement shall take precedence over any other documents that may be in conflict with it."

2 Contracts can sometimes be voided by successful assertion of 1 or more "contract defenses," such as (1) one side was not competent to enter into the contract, either due to age or mental illness; (2) one side had a "free way out" and really never provided any form of "consideration;"

(3) one side was under pressure and duress or other undue influence to sign; (4) one side engaged in fraud to procure the contract; (5) one side prevented the other from fulfilling its/her/his end of the bargain; (6) the original contract was changed with the agreement of all parties; (7) there was a mistake of fact or mistake of law prior to signing the contract; (8) the contract has an illegal purpose or act; (9) something happened, through no fault of either side, making the duties under the contract impossible to perform; (10) the side claiming the breach accepted the performance without claiming a breach had occurred.

3 Physicians use the term "partnership" carelessly. Generally, the corporate structure is better for a medical group than is a partnership because the former more effectively limits liability.

4 Radiology employment contracts often guarantee less time than is actually taken by members of the group, so as to give the group some maneuvering room in case of illness or departure of group members.

5 When a radiologist changes to a different job with a different claims-made policy, the new insurance company will sometimes pick up coverage for claims that may arise under the prior policy. This is called "nose" coverage. There is no guarantee, of course, that this will be available.

6 "Tail" coverage usually costs at least twice the last year's premium. So, for example, if a radiologist's premium for the last year before leaving the practice was $20,000, the tail could be expected to be at least $40,000 or more. Given the sums involved, the radiologist and group should have a contractual understanding of how this will be paid.

7 The basic types of "defined contribution plans" are (1) 401(k) plans, (2) money purchase plans, and (3) profit sharing plans. The amount of pre-tax dollars that can be set aside for retirement annually differs according to the type of plan, as do the employer's obligations under the plan. In 2004, 401(k) plans were limited to a maximum employee contribution of $13,000 (or $16,000 for individuals ages 50 and over). The employer may (but is not obligated to) contribute additional amounts to the plan. Under a money purchase plan, the employer may contribute up to 25% of the employee's salary to a limit of $40,000 maximum contribution. Once the level of contribution is set, the employer must make the contribution annually even if the company has no profits. Under a profit sharing plan, the employer may make discretionary contributions to the retirement plan annually based on profits with the same limits as under a money purchase plan. A combination of money purchase and profit sharing plans is possible. For a sobering experience, delve into the US Tax Code at http://www.fourmilab.ch/ustax/ustax.html.

8 It is important to know how the buy-in amount is determined. If the amount is based only on hard assets (such as equipment) it may be low even in a large practice, since equipment is often either old and of little value, or leased. If the amount is calculated on the value of accounts receivable, however, the amount could be large, even in a hospital-based practice.

9 In a recent California case, a noncompete agreement was held unenforceable against a radiologist because his buy-out did not reflect the true value of his interest in the practice. See *Hill Med. Corp. v. Wycoff*, 103 Cal. Rptr. 2d 779 (Ct. App. Jan 30, 2001) .

10 Courts vary in their interpretations of what is "reasonable" in this context as in many others. Because American law tends to favor free employability, courts often review these covenants with a higher level of scrutiny than other contract terms. Such covenants have been held invalid or only partially enforced for such reasons as (1) a hospital-based ER group had no "protectible" interest because the patients were held to be patients of the hospital, not the group; see *Duneland Emergency Physician's Med. Group, P.C. v. Brunk*, 723 N.E. 2d 963 (Ind. Ct. App. Feb 21, 2000); (2) enforcement of the covenant would be unfair because it would cause undue hardship for the departing physician and because the employer had created a hostile work environment; see *Sunder v. Mandalapu*, No. ATL-C-171-00 (N.J. Super. Ct. June 16, 2003); (3) the covenant could not be enforced against a group of nephrologists because public policy favors patient access to renal dialysis, see *Bio-Medical Applications of Tenn., Inc. v. Chary*, No. W1999-01727-COA-R3-CV, 2000 WL 1634201 (Tenn. Ct. App. Oct 13, 2000); (4) the covenant could not be enforced because a radius of 75 miles and term of 2 years were too much; see *Silvers, Asher, Sher & McLaren, M.D.s Neurology, P.C. v. Batchu*, No. WD57066, 2000 WL 387043 (Mo. App. Apr 18, 2000); (5) the group failed to show immediate and irreparable damage to itself if the covenant were not immediately enforced (called an "injunction"); see *Philadelphia Ear, Nose & Throat Surgical Assocs., P.C. v. Roth*, No. 2321 (Ct. Common Pleas Philadelphia County Mar 13, 2000). For a case involving interventional radiologists, see *Pensacola Radiology Consultants, P.A. v. Weingarten & Mietling*, Nos. 01-1197-CA & 01-1228-CA (Two Cases) (Fla. Cir. Ct. Escambia County Nov 1, 2001). For a case involving a radiologist leaving a group to do teleradiology, see *Drs. Hill and Thomas Co. v. Shaw*, No. CV-420530 (Ohio Ct. C.P., Cuyahoga County Nov 1, 2000).

11 Disputes over covenants noncompete represent a frequent source of litigation in physician employment contracts. At least 20 noncompete cases around the United States reached the appellate level between April 2000 and Dec. 2003, reported in the Health Law Digest © 2004 American Health Lawyers Association, Suite 600, 1025 Connecticut Avenue NW Washington, DC 20036-5405.

12 "Liquidated damages" clauses are not enforceable if they act as a "penalty." The legal justification for such clauses is the supposed difficulty, in the given circumstances, of establishing the actual amount of damages, so the parties agree on some amount beforehand. However, the amount must be "reasonable" to be enforceable. How one determines what is reasonable if establishing a fair amount is supposedly so difficult creates one of those interesting logical conflicts sometimes seen in the law. Cynics, of course, see this as typical of the legal system. For a case holding $180,000 in liquidated damages to be reasonable, see *Valley Med. Ctr. v. Schoos*, No. 46916-9-I (Wash. Ct. App. Dec 3, 2001). A case holding "an amount in excess of $100,000" as reasonable is *Eastern Carolina Internal Med. v. Faidas*, No. COA01-626, 2002 WL 957817 (N.C. Ct. App. May 7, 2002). For a case holding a liquidated damages clause unenforceable because it was part of an invalid noncompete clause, see *Junkin v. Northeast Ark.* Internal Med. Clinic, No. 00-434, 2001 WL 423077 (Ark. Apr 26, 2001) .

13 Arbitration clauses are, however, common in managed care and hospital contracts. Although the rationale behind these agreements is that they speed up the resolution of disputes at lesser cost than conventional litigation, there has been and continues to be considerable litigation regarding their enforceability. Nevertheless, the existence of these agreements tends to decrease the workload of courts, and courts tend to uphold them.

14 When negotiating an employment contract, it is worth asking if the practice is or has been involved in litigation with a former member or members.

HOSPITAL CONTRACTS

Many radiology groups have contracts with the hospitals where they work, guaranteeing them the exclusive right to practice radiology in the hospital, to the exclusion of other practitioners. The radiologist should be aware of 2 issues that can arise in this area:

1) The radiology group usually pays a price for having an exclusive contract with the hospital: the hospital will almost always insist that, in return for exclusivity, the group members surrender their due process rights. "Due process" is an integral part of "peer review"[1] and refers to the right of a member of the medical staff, or even an applicant for medical staff privileges, to know why those privileges are being revoked or denied, and to offer arguments challenging the decision. This involves the right to a hearing, often before the executive or credentials committee. If a radiology group has relinquished its due process rights, the hospital can replace it simply by nonrenewal of the contract, without the need for a medical staff hearing. This gives the hospital administration considerable power over the radiology group. Therefore, such a contract should be exclusive to the radiology group (ie, no one else can practice radiology in the department); otherwise the group is giving up a significant right for no return. Some groups are electing to practice in their hospitals without a contract; this puts their security primarily in the hands of their medical staff peers rather than the hospital administration.

> A strong relationship with the medical staff, based on clinical performance and service, may offer a radiology group more security than an exclusive contract with a hospital.

2) The legality of such exclusive contracts has been challenged many times, usually in a situation where the hospital has decided to replace one contracted radiology group with another, or where the existence of the contract prevents a doctor (who is not a member of the radiology group) from working in the radiology department. The challenge is usually based on either or both of 2 legal theories: (a) the contract is illegal under the antitrust laws because it improperly restrains competition, or (b) the offended radiologist was denied his or her medical staff due process rights. The first argument almost always fails because an impact on competition sufficient to implicate the antitrust laws cannot be shown.[2] The second argument usually fails because the courts have usually held that medical staff due process rights do not attach to an administrative decision of the hospital administration.[3]

ENDNOTES:

1 "Peer review" is the process whereby the medical staff attempts to assure quality of care in the hospital by monitoring both the clinical aspects of medical staff members' practices and their behavior. "Due process" attempts to protect staff members being reviewed from arbitrary or wrongful decisions by the reviewing body. Federal law protects medical staff peer review committees from liability for their decisions provided the professional review action is taken:

> "(1) in the reasonable belief that the action was in the furtherance of quality health care, (2) after a reasonable effort to obtain the facts of the matter, (3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3)." (Health Care Quality Improvement Act of 1986, 42 U.S.C. § 11101(1) (1994).

This law (that also established the National Practitioner Data Bank) was passed in reaction to *Patrick v Burget*, 486 U.S. 94 (1988), a case in which a physician successfully argued that he had been victimized by an unfair peer review proceeding, resulting in massive damages that resulted in closing of the defendant clinic and personal bankruptcy of several of its physician members.

2 The seminal case is *Jefferson Parish Hospital District No. 2 v. Hyde*, 104 S. Ct. 1551 (1984) in which the US Supreme Court held that an anesthesiologist's challenge to a hospital exclusive contract with another group was without merit because no antitrust injury was shown (ie, no impermissible effect on competition). A more recent case is *Villalobos v. Llorens*, No. CIV. 99-2034 (HL), 2002 WL 448623 (D.P.R. Mar 20, 2002) rejecting an anesthesiologist's antitrust challenge to an exclusive contract on similar grounds. Physicians asserting antitrust injury usually fail because, among other things, they fail to distinguish injury to themselves from injury to competition. The antitrust laws always protect the latter, but not usually the former. For a discussion of antitrust law in this context, see Zibners H., "Physician Contracting and Antitrust Law," in *Risk Management, Test and Syllabus*, Siegel BA, ed, American College of Radiology, Reston, Va, 1999.

3 See, for example, *Tenet Healthcare Ltd. v. Zamora*, No. 13-99-572-CV, 2000 WL 144173 (Tex. App. Feb 10, 2000) holding that a hospital is not required to extend due process rights to physicians excluded by an exclusive contract because such procedural requirements apply only when a physician's privileges had been reduced, suspended, or terminated because of

professional competence or ethical concerns and not to matters involving an administrative decision [as in this case]. This is a common legal rationale in these types of cases. *Van Valkenburg v. Paracelsus Healthcare Corp*., 606 N.W.2d 908 (N.D. Mar 3, 2000) is a similar holding on a similar basis.

Managed Care Contracts

In the usual or classic contracting situation, the parties voluntarily arrive at an enforceable agreement ("the contract") after more or less evenhanded bargaining. This is not the case in a situation where one party, because of superior economic power, imposes its will upon the other. This is called an "adhesion" contract. These types of "contracts" have been a favorite tool of managed care organizations and have generally been enforced by courts. In recent years, because of public pressure, the most egregious terms of these contracts have been declared illegal or circumscribed somewhat by many state legislatures.[1]

Managed care organizations may present their contracts with such epithets as "this is standard" or "just boilerplate" in hopes that the radiologist will sign without further inspection. However, unacceptable terms can sometimes be changed simply by being challenged. Areas of particular concern because of prior abuses include the following: [2,3]

1) **Administrative responsibilities** not clearly spelled out, such as utilization management, credentialing, or compliance with the managed care organization's or an extrinsic agency's standards.[4]

2) **Ambiguities allowing delays in payment**, such as failure to spell out when payments are due or the essential elements of a "completed claim form." Obtaining timely payment from managed care organizations and insurance companies has been a major problem for many practices. Requirements for "prompt" payment should be spelled out in the contract in detail.[5]

3) **Attempts to "lock in" reimbursement rates.** Fees should be negotiated separate from the other renewal aspects of the contract.

> The percentage of patients covered by managed care increased by 61.3% between l992 and l998.
>
> – American Academy of Orthopedic Surgeons, l998 Physician Census

4) **Attempts to conceal the reimbursement scheme.** The contract should specifically define the payment for each service. Some states now require this by law.

5) **Provisions prohibiting doctors from discussing treatment options with patients, commonly called "gag" clauses.** Most

states and the National Committee for Quality Assurance for Managed Care Organizations (a private credentialing organization) have now banned this previously common practice.

6) **The Health Insurance Portability and Accountability Act of l996** imposes extensive privacy requirements on health care entities, including doctors, hospitals, and managed care organizations. The radiologist should be alert for attempts to shift an unfair share of compliance accountability to him or her.

7) **"Carve-outs."** These are negotiated higher payments for expensive or unpredictable procedures. These should be specifically identified in the contract.

8) **Membership lists.** Since only the plan's members are eligible for services, the radiologist should seek a provision in the contract that services are performed in reliance on the payer's membership list and payment will be expected on that basis.

9) **"All products" provisions.** These require the radiologist who wants to participate in any one health plan offered by an insurer to accept all other plans the insurer offers, present or future, on terms dictated by the insurer.[6]

10) "**Hold harmless" clauses.** These require the radiologist to indemnify the insurer or health plan for any liability. Many malpractice insurance policies will specifically not cover such assumed liability.

11) **Unilateral amendments.** These allow the insurer to unilaterally change the agreement, often giving the radiologist short notice (30 days) with the option to accept the change or reject the entire contract.

12) **"Silent PPOs."** The contract may contain an "all payer" clause, under which the insurer or health plan can sell or rent its stable of providers to other entities such as insurance brokers without telling its contracted physicians. The result is that the doctors end up unknowingly providing discounted care to patients thought to be fee-for-service.

Many managed care contracts contain clauses mandating arbitration rather than litigation to resolve disputes, often justified on the grounds that it is more efficient. The radiologist should be aware, however, that many of the usual safeguards and requirements of legal procedure are surrendered when this method is used.[7]

Finally, the radiologist should know that when a managed care organization becomes insolvent, there is usually no other source of payment available.[8] As an ACR member, you can use the ACR's Contract Evaluation Checklist available at http://www.acr.org/s_acr/doc.asp?CID=1921&DID=6994. The checklist reviews common managed care contract provisions and offers general information.

ENDNOTES:

1 As examples, see Texas Administrative Code Rule 11.901 Health Maintenance Organizations Physician and Provider Contracts and Arrangements, which prescribes rules regarding such things as retaliation against physicians, required notice before dismissing a physician from a health plan, indemnification clauses, and payment rules; Also see California Insurance Code Section 10169-10169.510169 and Health and Safety Code Sections 1395-1399.5 & 1367-1374.16. There are 69 sections of the California Code dealing with managed care.

2 Harris SM. "Contract Language," AM News, March 4, 2002 and April 1, 2002.

3 In May, 2000, the California Medical Association and several other states sued a number of for-profit managed care organizations under the RICO (Racketeer Influenced and Corrupt Organizations) Act, alleging that their pattern of activity vis-à-vis physicians and patients amounted to racketeering. On May 22, 2003, at least one of these organizations entered into a settlement with the plaintiffs, agreeing to payment of money damages and reform of some procedures which resulted in delayed payment. See the California Medical Association Web site at http://www.cmanet.org/publicdoc.cfm/2/1/presssection2/269.

4 Items 1 -8, Harris SM. Op. cit.

5 These should be very specific, such as billing form to be used; patient's name and ID number; claim date; date of birth; group name and number; provider's name and identification number; dates and location of services; description of procedures; diagnosis code; secondary diagnosis code; most current ICD version; procedure codes; DRG; units; modifiers and amount billed for each procedure; itemized claim statements and/or beneficiaries' medical records if requested by payer. Some states have passed laws requiring prompt payment if claims are properly submitted. As an example, see Ohio Revised Code Title [39] XXXIX Insurance § 3901.38, which requires payment of completed claims within 24 days.

6 Items 9-12, Guadagnino C. "Managed Care Contracting Strategies," Physician's News Digest, Inc., July 2000. Available online at http://www.physiciansnews.com.

7 The existence of an arbitration agreement does not always avoid litigation. As examples, consider *Armendariz v. Foundation Health Psychcare Servs., Inc.*, 6 P.3d 669 (Cal. Aug 24, 2000) , holding an arbitration agreement unenforceable because of terms so unilateral as to be a contract of adhesion and *Garfinkel v. Morristown Obstetrics & Gynecology Assocs.*, 773 A.2d 665 (NJ June 13, 2001), holding a doctor's employment agreement unenforceable because it was too ambiguous.

8 A common payment arrangement, particularly in California, involved a managed care plan contracting with a physician organization called an Independent Practice Association, which then subcontracts with its physician members to provide medical services to the managed care plan's patients. An attempt by the California Medical Association to hold a managed care plan liable for payments to physicians after several IPAs became insolvent was rejected by the court. See *California Medical Association, Inc. v. Aetna U.S. Healthcare of California, Inc*., 114 Cal. Rptr. 2d 109 (2001). Also, see *Desert Healthcare Dist. v. PacifiCare*, No. E02961, 2001 WL 1632303 (Cal. Ct. App. Nov 30, 2001), and *California Emergency Physicians Med. Group v. PacifiCare of Cal.*, No. D040034 (Cal. Ct. App. Sept 5, 2003), further examples of inability to recover payment for health care services.

3. Regulatory Issues

FRAUD AND ABUSE

False Claims Act

Medicare Fraud and Abuse

Overview

Medicare is a federal health insurance program that provides benefits to the nation's elderly and disabled.

All radiologists and other physicians who wish to participate in Medicare must apply for and receive a Unique Provider Identification Number (UPIN). Participation in Medicare, almost always a substantial portion of any radiology practice, carries with it a variety of requirements and conditions. A key condition is that any claim submitted to Medicare be valid under the program's complex coding and billing requirements. Failure to abide by these requirements may expose a radiologist to allegations of Medicare fraud and abuse.

Actual Medicare coding and billing requirements are continually evolving, reflecting the changing nature of medicine and well as the government's on-going efforts to improve the efficiency of the program. Claims submitted to Medicare must reflect the medical service(s) provided that are "covered" by the program. "Coverage" refers to those medical products and services that are included in the Medicare program, as either defined in the laws that govern Medicare or in regulations written by those who administer the program. For instance, Medicare does not cover screening or preventative health services, unless specifically allowed for by law, such as is the case with mammography for breast cancer screening.[1] In any event, when a new medical product or service is developed, a determination of whether Medicare covers that new technology must be made by program administrators at either a local or national level.

Coding is the process whereby a covered medical service is assigned to an existing code that accurately reflects the services rendered. This code is subsequently used by Medicare and other health insurance carriers to render payment. Accurate coding is crucial. The assigned code

cannot exaggerate the service provided (so-called "up-coding"), such as when 2 views of the cervical spine were obtained and the patient billed for 4 or more views, nor can Medicare be billed for the discrete parts of a study or procedure when a separate code for the complete service exists (known as "unbundling"), as would occur if a radiologist billed for multiple single views of a shoulder instead of a standard, multiple view shoulder series. If there is no code that accurately reflects a study or procedure, a generic "unlisted" code that does not represent a specific service must be billed and detailed information provided, often in the form of documentation outlining the patient's clinical circumstances, the service in question and why it was necessary, and support for the charges sought. Reimbursement for unlisted codes is often unpredictable and claim denials not infrequent. You may read a thorough overview of the reimbursement and coding system that radiologists and radiation oncologists must confront by Thorwarth WT Jr at J Am Coll Radiol 2004;1:48-53.

Medicare claims must be submitted by an individual or institution able to legally bill the program for the services provided. This requirement can be an issue in the teaching hospital environment, where physicians' professional services are often a combined effort of staff physicians and physicians-in-training, such as interns, residents, and fellows. As the Medicare program contributes substantial financial resources to the salary support of physicians-in-training participating in Accreditation Council for Graduate Medical Education (ACGME)-accredited programs through its Part A[2] payments to institutions, there is a long-standing policy barring such trainees from billing Medicare for services provided as part of their accredited training programs. In practice, this rule allows physicians-in-training who are otherwise qualified to bill Medicare to submit claims for services outside of their duties as trainees, such as when a vascular-interventional radiology fellow in an ACGME-accredited program moonlights as an emergency radiologist. Conversely, should that same fellow be on call for vascular radiology while moonlighting and the need for an emergent arteriogram arise, there is little doubt that he or she could not legally bill Medicare for professional services related to that arteriogram.

Similarly, staff physicians at teaching institutions cannot bill Part B, the professional services component of Medicare, for services primarily provided by their trainees. This means that staff radiologists must personally interpret diagnostic studies, or review the trainee's interpretation, with the latter requiring more than a countersignature on an official report. With regard to interventional procedures, a "surgical" standard applies, which requires that the staff physician be present during all critical portions of the procedure and immediately available to furnish services during the entire procedure. Though what comprises the critical portions of a procedure depends on the service being provided, there is little doubt that interventional radiologists must be physically present for some portion of procedure for which they bill Medicare.[3]

Fraud and Abuse Actions

Medicare fraud and abuse claims may spring from a variety of actions, including billing for services not covered by the program, products and services not actually provided, and incorrect coding. Most claims rely on the federal False Claims Act, which only requires that an individual "knowingly" submit a false claim to the government; the claim itself does not have to be paid. Under current law, the "knowingly" requirement is met if the individual or organization submitting the claim has actual knowledge of its falsehood, acts in deliberate ignorance of the truth or falsity involved, or acts in reckless disregard of the truth or falsehood. In practice, this standard does not require specific intent[4] to defraud, meaning that an obviously flawed billing system that repeatedly submits incorrect claims to Medicare could qualify. Furthermore, the government maintains that the absence of a Medicare billing compliance program is evidence of the "deliberate ignorance" that can demonstrate knowledge of fraud and abuse.

> [Medicare] paid a podiatrist $143,580 for performing surgical procedures on at least 4,400 nursing facility patients during a 6 month period. For these services to have been legitimate, the podiatrist would have had to serve at least 34 patients a day, 5 days a week.
>
> – GAO testimony before the U.S. Senate, June 26,1997

A successful False Claims Act action carries with it severe penalties. Providers and institutions found liable may have to pay 3 times the actual amount paid by the government for the fraudulent claim, plus up to $11,000 in penalties for each false claim submitted. Returning to a previous example, a radiology practice that billed Medicare for 3 single views

of the shoulder instead of a multiple-view shoulder series on 100 patients would face not only several thousand dollars in repayment, but also face civil penalties that could range into the millions of dollars. More importantly, the practice or its physicians may be subject to criminal penalties or exclusion from participation in Medicare. Such exclusion can make a physician virtually unemployable and could bankrupt a practice.

The Office of Inspector General of the Department of Health and Human Services has enforcement authority over many Medicare fraud and abuse laws and thus is the source of many Medicare fraud and abuse cases. Given the cost of improper Medicare claims, the government has long-standing policies to pursue such cases where they are discovered or suspected. In the last decade, OIG scrutiny has been applied to teaching hospitals under the Physicians at Teaching Hospitals or "PATH" audit program, which examined Medicare claims for attending physician services which may have actually been performed by trainees. The PATH program resulted in the payments of tens of millions of dollars in settlements by a number of well-known teaching institutions.[5]

Bringing False Claims Act actions is not limited to the government. "Qui tam" or so-called "whistle blower" provisions of the law allow private individuals and organizations to bring actions and be financially rewarded if the action is ultimately successful. Given that a whistle blower may be awarded 10–30% of a settlement or judgment that may involve millions or more, these provisions provide a strong incentive to report suspected Medicare fraud.[6] In the past, present and former employees of healthcare organizations have routinely come forward with such complaints.

Radiology Residents and Medicare Fraud and Abuse

Radiology residents typically are not involved in the coding and billing functions that result in Medicare fraud and abuse claims and, accordingly, face little personal exposure should a claim be brought. However, radiology residents must be careful to avoid personally submitting claims to Medicare that arise from any service provided program beneficiaries as part of their actual accredited residency program. Doing so will virtually eliminate any personal liability for Medicare fraud and abuse.

ENDNOTES:

1 Medicare pays for screening mammography for all women with Medicare age 40 and older every 12 months, as well as for 1 baseline mammogram between ages 35 and 39, with a 20% co-payment. Of course, a person is not eligible for Medicare coverage until age 65 unless disabled or on renal dialysis. Medicare also provides coverage for cervical, colorectal, and prostate cancer screening.

2 The Medicare program has 2 components: Part A is hospitalization insurance which is usually fully covered; Part B is medical insurance which covers physician fees, outpatient hospital care, and some other medical services that Part A does not cover, such as the services of physical and occupational therapists, and some home health care. A monthly premium is charged for Part B coverage. Medicare + Choice, or Part C, plans are a largely unsuccessful attempt to shift recipients into managed care plans.

3 Many physicians feel that Medicare reimbursement rates are too low. Since Jan. 1, l988, it has been possible for a physician to "opt out" of Medicare, meaning that the physician can no longer see Medicare patients unless doctor and patient have entered into a private contract under which the patient agrees to pay out-of-pocket an agreed-upon fee. After a 90-day grace period, this decision by the physician cannot be rescinded for at least 2 years. For most radiologists this is not a feasible option, since the majority of radiology practices are conducted at least partially in hospital environments where Medicare patients must be seen (because the hospital has assumed the obligation to do so). Therefore, most radiology practices accept Medicare "assignment," meaning that they agree to accept the Medicare-approved charge as full payment, 80% from Medicare directly and 20% from the patient or the patient's private insurance (often called "Medigap" insurance). Balance billing for amounts in excess of the Medicare-approved amount is illegal under this arrangement.

4 "Specific intent" is a legal term of art, meaning that the accused intended not only to commit the act but also to violate the specific law making that act illegal. This makes establishing liability significantly more difficult, since an individual often knows in general terms that an act is wrongful without knowing which specific law is being violated.

5 Between December 1995 and May 2003, 19 US medical schools paid the government a total of $249.1 million as a result of the PATH audit initiative. The largest single payment was $30 million and the smallest was $800,000. See the American Association of Medical Colleges at aamc.org/start.htm.

6 Since 1986, total qui tam recoveries have exceeded $3.5 billion, and more than 3,000 qui tam cases have been filed, most of them against those who do business in the health care industry. For a brief discussion of qui tam implications in a false billing situation, see Zibners H. "Teleradiology," Question 57 at pp. 111-112, in *Risk Management, Test and Syllabus,* American College of Radiology, Reston, Va, 1999.

Antikickback Statute

The federal antikickback statute[1] makes payment for referrals illegal. It states that "…whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe or rebate (directly or indirectly, overtly or covertly, in cash or in kind …. in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under [Medicare] or [Medicaid] shall be guilty of a felony and… shall be fined not more than $25,000 or imprisoned for not more than 5 years, or both." Be aware that under this law, it is not necessary that an improper referral actually occurred, only that the payment might induce a referral. Also, the fact that there may be proper reasons for the referral is no excuse, if one of the reasons for the referral was the improper inducement.[2]

Again, the radiologist could be held liable for the improper actions of an employee of which he or she was unaware. The government has promulgated numerous "safe harbors"[3] that, if the requirements are met, insulate individuals from prosecution for conduct which would otherwise be illegal.

ENDNOTES:

1 The Medicare and Medicaid Patient Protection Act of 1987 (42 U.S.C. § 1320a-7b).

2 *United States v. Greber*, 760 F.2d 68, 71 (3rd Cir.), cert. denied, 474 U.S. 988 (1985).

3 Found at 42 C.F.R. § 1001.952.

Stark law

The "Stark law"[1] prohibits the referral of patients or the submission of Medicare or Medicaid claims for "designated health services," including radiology and radiation therapy services if the referring physician or an immediate family member has an ownership or investment interest in or a compensation arrangement with the entity to which the referral is made. If a financial relationship exists, then either an exception applies and referrals are still permitted, or the referral is illegal. The Stark law specifically exempts the provision or supervision of services by radiologists or radiation oncologists in their own offices or departments provided these have been requested by another physician. However, the law could be impacted if, for example, a radiologist were being paid to provide services in another physician's office or clinic. Liability here can be avoided through what is called a "personal services" exception, the requirements of which are specific, including that the agreement be in writing, cover at least a 1-year term, and that compensation be at fair market value. Penalties for violation of this law could include exclusion from the Medicare program, and payment of up to $15,000 for each service improperly billed and up to $100,000 for a scheme to circumvent this law.

ENDNOTE:

1 Social Security Act, sec. 1877; 42 USC § 1395nn.

ANTITRUST

This is a legally complex subject, any significant discussion of which is beyond the scope of this overview. At a minimum, however, the radiologist should be aware of the following:

1) The antitrust laws apply to physicians.[1] Lack of awareness of the implications of an antitrust violation has resulted in the bankruptcy and dissolution of at least one medical group.[2] These laws can be implicated in physician disputes over medical staff privileges,[3] disputes over exclusive contracts,[4] fee disputes with managed care organizations and insurance companies,[5] and efforts by physicians to organize.[6]

> The antitrust laws were originally passed to combat the growing economic power of railroads. For many years they were used to fight organized labor.

2) Certain antitrust violations are considered so onerous that the courts have devised a special name for offenses falling into this category. These are called "per se offenses." No legal justification for these activities is permitted once their existence has been shown (ie, one is not permitted to offer justification or explanation as a defense). These are attempts at price fixing (arranging fees with other doctors who are not your business partners), dividing markets (dividing areas of practice with other doctors who are not your business partners), and boycott (organizing other doctors to boycott an HMO or insurance company for more money or other benefits).

3) Penalties for violation of these laws can be severe, including heavy fines and prison terms.

ENDNOTES:

1 *Goldfarb v. Virginia State Bar* 421 U.S. 773 (1975)

2 Op. cit., Note 29; *Patrick v. Burget* 486 U.S. 94 (1988)

3 Ibid, *Patrick v. Burget*

4 Op. cit., Note 30

5 The seminal case is *Arizona v. Maricopa County Medical Soc.*, 457 U.S. 332 (1982) where the US Supreme Court held as per se (this term is defined in the body of the text, above) illegal an attempt by physicians with separate practices to set a mutually agreed-upon fee schedule for dealing with insurance companies. A more recent example is *U.S. v A. Lanoy Alston, D.M.D.*, P.C., 974 F2d 1206 (9th Cir. 1992), a case where a group of Arizona dentists were criminally prosecuted by the US Justice Department after they got together and wrote letters, all drafted by one of them, to prepaid dental plans demanding more money. They were not imprisoned, although this was a possible outcome. Another recent example is *US v Federation of Physicians and Dentists, Inc.*, No. 98-475, (US Dist. Ct. Del.). The FPD, an organization that primarily represents employed physicians, began in l996 to recruit mostly orthopedic surgeons in Delaware and other states on the basis that it could legally represent them in fee negotiations. The insurance company thus could not negotiate with physicians individually, which of course it preferred. The federal government sued on the basis that this represents a price-fixing conspiracy and boycott, both per-se offenses. In November 2002, the parties entered into a settlement under which FPD agreed not to engage in collective bargaining for independent physicians nor exchange competitive information among them, but could analyze and compare offered contract terms in a manner which does not communicate competitively sensitive information among them nor recommend specific contracts. This so-called "messenger model" means of physician-payer bargaining is legal, provided the above rules are obeyed.

6 An example of physicians' unsuccessful attempt to unionize is *AmeriHealth Inc. / AmeriHealth HMO and United Food and Commercial Workers Union, Local56, AFL-CIO, Petitioner*. Case 4-RC-19260 [329 NLRB No. 76]. The union sought certification from the National Labor Relations Board (NLRB) as the collective bargaining representative for 652 physicians in New Jersey who claimed that AmeriHealth HMO exerted such control over them that they were de facto employees of the HMO, and, therefore, eligible to organize as a union. The NLRB denied the petition, on the grounds that the doctors had sufficient control over their own activities to be deemed independent contractors, not employees. Only about one sixth of US physicians are employees under the legal definition of "employee," which has mostly to do with degree of control by the "employer."

FDA REGULATION OF NEW MEDICAL PRODUCTS

Overview

The US Food and Drug Administration (FDA) has broad authority to regulate the marketing of drug, biologics and medical devices within the United States. Though the agency's activities have a profound impact on health care, they are poorly understood by practitioners and patients alike. This lack of understanding contributes to a climate of confusion and, not infrequently, fear on the part of providers concerning FDA's activities.

Under the Food, Drug, and Cosmetic Act (FDCA),[1] the FDA is charged with ensuring that marketed medical products are safe and effective for their approved or cleared uses. Under this regulatory system, it is illegal to market a new drug, biologic, or medical device in the United States without the agency's explicit permission. In addition to this gatekeeper function for new medical products, the agency also has power to address safety issues that may arise in drugs, biologics, and devices that are already legally marketed. FDA regulation is comprehensive for new and established products alike, with the agency overseeing both manufacturing and product claims, whether such claims are made in the FDA-approved labeling, product advertisements, or other forms of promotion.

In practice, FDA's mandate for safe and effective medical products means that medical products are approved or cleared by the agency for a specific clinical application(s). This clinical application is listed in the product's FDA-approved labeling, along with explicit directions on the product's agency-sanctioned use. Use for indications outside of this official labeling are commonly referred to as "off label" uses. Generally speaking, manufacturers must limit product claims to those indications contained within that approved labeling, though a company may respond to an unsolicited physician request for product information on an off-label use with non-abridged, peer-reviewed journal articles.

Off-Label and Unapproved Use of Medical Products

While the FDA's authority is broad, it is focused on the actual marketing of medical products, not their use by licensed physicians in the care of their patients. This is reflected in the long-standing Practice of Medicine Doctrine, which allows physicians to use FDA-approved or cleared products in any way he or she sees fit in the care of specific patients. However, the doctrine does not permit a physician to engage in activities that would amount to marketing the off-label use, such as high-volume use in conjunction with aggressive advertising, though it is quite unclear what activities would trigger regulatory scrutiny. In addition, the doctrine cannot be invoked where obtaining human clinical data is the primary purpose of a medical procedure.

Experimental Drugs and Devices

As FDA regulations bar the distribution of any medical product that is neither approved nor cleared for use, the agency provides for limited, controlled exceptions in the case of investigational clinical trials designed to establish the safety and effectiveness necessary to gain marketing approval. The mechanisms include investigational new drug (IND)[2] applications for drug and biologics, and investigational device exemptions (IDEs)[3] for medical devices. Both INDs and IDEs are complex mechanisms that define rigid protocols for the investigational product's use in humans, and include elaborate informed-consent provisions. INDs and IDEs may be obtained by either a commercial entity supporting the research, known as a "sponsor" or a clinical investigator. Depending on the type of product and the risk involved, obtaining an IND or IDE may involve an institution's own institutional review board (IRB)[4], or the IRB and FDA. Use of a medical product distributed under an IND or IDE outside of its approved protocol may only occur with the FDA's consent, or under very limited emergency circumstances. Routine use of an investigational product under the latter circumstance will almost certainly trigger FDA scrutiny.

> The FDA and HHS have suspended clinical research studies at several institutions across the country due to the rising number of research related deaths.
>
> – Tector LM & Allen ME, Group Practice Journal, September 2001

Penalties for Violation of FDA Regulations

Violation of FDA regulations can bring a variety of penalties to the involved parties. With regard to companies, monetary fines and increased agency oversight are commonly employed. Institutions such as hospitals occasionally have experienced complete or partial shutdowns of their clinical research programs, generally for severe or repeated violations of safety- or informed consent-related regulatory provisions that have resulted in patient injury.[5] Individual investigators also have had their ability to conduct clinical trials limited or curtailed by the agency.

Though many physicians fear agency action directed at them as individuals, such actions are quite rare, as the FDA focuses its enforcement efforts on companies and institutions. When they do occur, actions against specific physicians are almost always related to aggressive, arguably commercialized use of medical products in a non-FDA sanctioned fashion, or to instances involving clinical experimentation where disregard for agency regulations resulted in a safety risk to patients or actual patient injury. Practically speaking, off-label use, so long as conducted in concordance with a specific institution's local human research protection policies (including IRB approval, if required), does not incur regulatory consequences at the federal level.

ENDNOTES:

1 The act itself is available online at http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm

2 The investigational new drug application process is available online at http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm.

3 Investigational device exemption information is available online at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=812.35.

4 An Institutional Review Board Guidebook detailing the rules and requirements is available from the Office of Human Research Protections of the US Department of Health and Human Services at http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm.

5 A recent detailed discussion of the legal issues involved in human research, including recent litigation and investigations, is "Clinical Trials: Protecting The Subject, Avoiding Liability, and Managing Risk" by Elizabeth A. Price, JD & J. Andrew Lemons, JD, January 2002, available from the American Health Lawyers Association, Suite 600, 1025 Connecticut Avenue NW Washington, DC 20036-5405, Phone: (202) 833-1100, Fax: (202) 833-1105, or www.healthlawyers.org.

Teleradiology

Almost all radiologists are now familiar with this technology, which allows transmission of images from room to room or continent to continent with almost equal ease. Increasing acceptance of telemedicine is reflected in the federal government's easing of restrictions on payment for its use.[1] The increasing demand for 24 hour services in radiology has spawned the growth of the "nighthawk" practice, which provides after-hours coverage for other radiology practices on a contract basis, frequently across state lines and increasingly outside the United States. The radiologist should be aware of several potential issues that may arise in this context.

First, there is little doubt that the teleradiologist is exposed to malpractice liability, regardless of geographic separation of radiologist and patient.

Second, medical malpractice insurance may not cover activities in another state, let alone in another country. It may be necessary to obtain an addendum to the insurance contract agreeing to cover the out-of-state or out-of-country activity or obtain insurance in the "sending" state or country.

Third, licensure to practice medicine is a prerogative of the states; there is no national medical license. Therefore, before interpreting images from another state one must determine whether that state requires full licensure or offers some type of limited telemedicine license to out-of state teleradiologists. The majority of states require full licensure.

Both the "receiving" teleradiologist and the "sending" radiologist must be aware of these issues. If the teleradiologist to whom referral is made were to be deemed uninsured or unlicensed, the "sending" radiologist might become the only source of liability payment.[2]

ENDNOTES:

1 Medicare, Medicaid, and SCHIP Improvement and Protection Act of 2000 (H.R. 5661), effective Oct 1, 2001, authorizes Medicare/Medicaid payment in certain situations, primarily rural areas.

2 For a more complete discussion of legal issues in teleradiology see Zibners H., "Case 11: Teleradiology," in *Risk Management, Test and Syllabus,* Siegel BA, ed, American College of Radiology, Reston, Va, 1999. See also Hoffman T. and Shields B., "Teleradiology: An Underdeveloped Legal Frontier," in *ACR Bulletin*, Sept 2005.

Authentication of reports

In many radiology practices, radiologists routinely authenticate their colleagues' reports by signing them. This is done in the absence of the radiologist who actually performed or interpreted the examination in order to facilitate timely turnover of reports. Although this practice is a virtual necessity in many situations, it raises potential legal problems.

First, certifying an examination which one has not personally performed or interpreted raises some obvious potential difficulties. The narrow legal point of view suggests that one is certifying the report not only for typographical, but also for factual accuracy. Careful review of your associates' report can certainly satisfy the former, but not the latter. Since the actual interpreting radiologist's typed name is on the report, as well as the signature or initials of the authenticating radiologist, in the case of a malpractice suit both radiologists might well be named. The degree of liability of the authenticating radiologist may be uncertain, but even being named in a malpractice claim can result in negative consequences. Malpractice insurance coverage may be denied or premiums could be raised as a result. It could be several years before the authenticating radiologist name is dropped from the claim or lawsuit and during this time legal expenses will accrue and any application for privileges must reflect the radiologist's involvement in the claim or lawsuit. No actual medical malpractice case known to the authors has directly addressed this situation.

Second, Medicare and Medicaid regulations, at least insofar as hospitals are concerned, require that reports be signed by the doctor who performed or interpreted the examination.[1] On the other hand, the Joint Commission on Accreditation of Health Care Organizations (JCAHO), no longer requires physician signatures on verbal orders or certain other record entries, including radiology reports.[2] This confuses the issue somewhat since Medicare and Medicaid generally accept JCAHO certification for their own purposes.[3] However, since the JCAHO is a private organization, the existing Medicare and Medicaid regulations should be the controlling rule.

The increasing availability of computers and Web-based systems that allow for signing of reports remotely (for instance, from home) may eventually obviate this problem.

ENDNOTES:

1 42 Code of Federal Regulations Sec. 482.24, Conditions of Participation for Hospitals, Condition of Participation: Medical Record Services (c)(1) and (c)(1)(i) state, "All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished. The author of each entry must be identified and authenticate his or her entry." 42 CFR Sec. 482.26 Condition of participation: Radiologic Services, states that "The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations."

2 See the American College of Radiology Legal Department Web site at http://www.acr.org/publications/members_only/bulletin/10-96/oct96_13_special.html.

3 SEC. 1865. *[42 U.S.C. 1395bb]* (a) (Social Security Act).

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Appendix

MEDICAL-LEGAL TERMS

Abandonment: Termination of a physician-patient relationship without reasonable notice and without an opportunity for the patient to acquire adequate medical care, resulting in some type of damage to the patient.

Admissibility: Evidence that may properly be introduced in a legal proceeding. The determination as to admissibility is based on legal rules of evidence and is made by the trial judge or screening panel.

Admissions: Statements by a party that are admissible in evidence as an exception to the hearsay rule. In a malpractice proceeding, an admission would typically be a statement of culpability by the defendant.

Affidavit: Voluntary, written statement of facts made under oath before an officer of the court or before a notary public.

Affirmative defense: A response by the defendant to allegations in the complaint, that even assuming the alleged facts to be true, would constitute a defense. In effect, by presenting an affirmative defense, a defendant tries to avoid all or part of the liability.

Aggregate: The total dollar amount of claims that will be paid under any one insurance policy during the coverage period. For example, a residency program might have $1 million/$3 million coverage, which means that a resident is insured for up to $1 million per incident and up to $3 million per year.

Allegation: Statement of a party to an action, made in a pleading, setting out what the party expects to prove.

Answer: A legal document containing a defendant's written response to a complaint or declaration in a legal proceeding. The answer typically either denies the allegations of the plaintiff or makes new allegations as to why the plaintiff should not recover.

Appeal: The process by which a decision of a lower court is brought for review to a court of higher jurisdiction, typically known as an **appellate court**.

Appellate court: The court that reviews trial court decisions. Appellate courts review the transcript of the trial court proceedings and determine whether errors of law were committed by the trial court.

Bailiff: An officer of the court who is in charge of courtroom decorum, directs witnesses to the witness stand, and attends to jurors.

Battery: The unauthorized and offensive touching of a person by another. In medical malpractice cases, battery is typically contact of some type with a patient who has not consented to the contact. Battery can be either a civil or a criminal offense.

Burden of proof: The necessity or duty of affirmatively proving a fact or facts in dispute. The plaintiff typically has the burden of proof.

Captain of the ship: A doctrine whereby the surgeon in charge of a medical team is liable for all the negligent acts of the members of the team.

Case: An action or cause of action; a matter in dispute; a lawsuit.

Case law: Legal principles derived from judicial decisions. Case law differs from statutory law, which is enacted by legislatures.

Cause of action: A set of alleged facts that a plaintiff uses to seek legal redress.

Clerk of the court: The person responsible for the administrative functions of a court. During a trial, the clerk administers oaths to witnesses, receives and marks exhibits admitted into evidence, and requests the verdict from jurors.

Collateral source: A rule of law that prevents a court from subtracting from the damage award any payments that the plaintiff has received from workmen's compensation, insurance, government benefits, sick-pay benefits, or other sources.

Common law: The body of law passed down to American colonies by the British legal system and has been interpreted and refined by case law.

Comparative negligence/contributory negligence: Affirmative defenses, one or the other of which is recognized in all jurisdictions.

- ***Comparative negligence:*** An affirmative defense recognized in some jurisdictions that compares the negligence of the defendant to that of the plaintiff. The plaintiff may recover damages from a negligent defendant even if the plaintiff and defendant are equally at fault. Only when the plaintiff's negligence is greater than the defendant's can there be no recovery. The plaintiff's damages are reduced, however, by the percentage that his or her own fault contributed to the overall damage.
- ***Contributory negligence:*** An affirmative defense that prevents any recovery against a defendant when the plaintiff's own negligent actions contributed to his or her own injury, even though the defendant's negligence may also have contributed to the injury.

Complaint: A legal document that is the initial pleading by the plaintiff in a civil lawsuit. In some jurisdictions, a complaint is known as a declaration. The purpose is to give a defendant notice of the alleged facts constituting the cause of action. The complaint is usually attached to the summons.

Contingency fee: An agreement between a plaintiff and his or her attorney by which the plaintiff agrees to pay the attorney a percentage of any damages recovered.

Court reporter: A professionally trained stenographer who transcribes deposition or trial testimony.

Court trial: A trial without a jury, wherein a judge determines the facts as well as the law.

Culpability: Being at fault; deserving reproach or punishment for some action. "Culpable" connotes wrongdoing or errors of ignorance, omission, or **negligence**.

Damages: The sum of money a court or jury awards as compensation for a tort. The law recognizes certain categories of damages, which vary among jurisdictions and can be inconsistent and imprecise. The main categories are general, special, and punitive, or exemplary, damages. *General damages* are typically intangible damages, such as pain and suffering or interference with ordinary enjoyment of life. *Special damages* are out-of-pocket damages such as medical expenses, lost wages, and rehabilitation expenses. *Punitive, or exemplary, damages* may be awarded to a plaintiff in cases of intentional torts or gross negligence to punish the defendant or deter others from similar actions.

Declaration: See **complaint**.

Deposition: A **discovery** procedure by which each party can question the other party or anyone who may be witness. Depositions are conducted under oath before trial and are admissible at trial under certain circumstances.

Directed verdict: A ruling by the trial judge that as a matter of law, the verdict must be in favor of a particular party. A verdict is usually directed as a result of a clear failure to meet the burden of proof, sometimes referred to as a failure to establish a **prima facie** case.

Discovery: Pretrial procedures that allow parties to learn of **evidence** so as to minimize the element of surprise at the time of trial. These procedures typically include **interrogatories** and **depositions,** but also can include requests for admission of facts and requests for genuineness of documents.

Dismissal: A legal denial. To dismiss a **motion** is to deny it; to dismiss an appeal to affirm the **judgment** of the trial court.

Due process: Legal procedures that have been established in systems of jurisprudence for the enforcement and protection of private rights. Often the term means the right to a fair trial.

Duty: An obligation recognized by the law. A physician's duty to a patient is to provide the degree of care ordinarily exercised by physicians practicing in the same community or area of specialization.

Evidence: Facts presented at trial through witnesses, records, documents, or concrete objects, to prove or defend a case. Types of evidence include the following:

- ***Circumstantial evidence:*** Facts or circumstances that imply that the principal facts at issue actually occurred
- ***Direct evidence:*** Proof that establishes a fact directly without the need to prove any other fact
- ***Demonstrative/real evidence:*** The use of articles or objects rather than the statement of witnesses to prove a fact in question
- ***Material evidence:*** Proof of facts that directly affect an element of the cause of action, such as testimony on the standard of care in a medical malpractice case
- ***Opinion evidence:*** Testimony of an expert witness based on special training or background, rather than on personal knowledge of the acts in issue
- ***Prima facie evidence:*** A level of proof that is sufficient to establish the fact, and if not rebutted, becomes conclusive of the fact

Expert opinion: The testimony of a person with special training, knowledge, skills, or experience in an area relevant to the resolution of a legal dispute.

Federal courts: Another system of trial and appellate courts like state courts, but that only accept certain types of cases. Malpractice cases are generally not filed in the federal courts unless the patient is from one state and the health care provider is from another state.

Hearsay: An out-of-court statement offered in court to prove the truth of facts contained in the statement. Hearsay is generally not admissible. There are, however, exceptions to the hearsay rule, such as an admission against interest or the learned treatise exception.

Hostile witness: A witness whose position or viewpoint is adverse to that of the attorney who called him or her to the stand.

Hung jury: A jury that cannot reach a decision that constitutes a verdict in its jurisdiction, frequently after lengthy deliberation. A hung jury results in a mistrial, which, in most circumstances, means that that the case will be retried before a new jury.

Hypothetical question: A question that solicits the opinion of an expert witness at a trial or **deposition** based on a combination of assumptions and facts already introduced in evidence.

Informed consent: A legal doctrine that requires a physician to obtain the patient's consent for treatment rendered or an operation performed. In situations requiring informed consent, the physician may be liable for violating the patient's rights if informed consent has not been obtained, regardless of whether the treatment was appropriate and rendered with care. See **battery**.

Interrogatories: A discovery procedure in which one party submits a series of written questions to the opposing party, who must answer in writing under oath within a certain period. The answers are admissible at trial under certain circumstances.

Joint and several liability: A legal doctrine whereby each individual defendant is responsible for the entire amount of **damages** awarded against all defendants.

Judgment: The final entry in the record of a case that is binding on the parties unless overturned or modified on appeal. A judgment typically consists of a

finding in favor of one or more of the parties and an assessment of damages and costs.

Jury trial: A trial in which 6 or 12 registered voters are impaneled to hear evidence, determine the facts, and render a **verdict**. In most states, the verdict must be unanimous.

Loss of consortium: A claim for damages by the spouse of an injured party for loss of care, comfort, and society and interference with sexual relations.

Malpractice: Professional negligence. In medical terms, it is the failure to exercise that degree of care that is taken by reasonably careful physicians with like qualifications in the same or similar circumstances. The failure to meet this acceptable **standard of care** must cause the patient injury.

Material risk, material facts: In **informed consent**, a material risk is one that, if communicated to the patient, would induce him or her either to accept or decline treatment; material facts are those that are must be disclosed to the patient before an informed decision can be made.

Motion: Written or oral court plea requesting that the judge make a ruling or order affecting the lawsuit.

Negligence: Legal cause of action involving the failure to exercise the degree of diligence and care that a reasonably and ordinarily prudent person would exercise under the same or similar circumstances.

Periodic payments: Damages paid to a plaintiff over a period of time rather than in a lump sum. If a state law permits, periodic payments may be ordered when the damages exceed a certain amount.

Pleadings: First phase of a lawsuit, during which the issues in dispute are identified and clarified, including the plaintiff's **cause of action** and the defendant's grounds of defense.

Preponderance of the evidence: The greater weight of evidence, or evidence that is more credible or convincing.

Prima facie case: A case that will survive a motion for a **directed verdict** by the defense and requires the defense to offer evidence on its own behalf.

Privileged communication: Confidential communication between individuals that has a special legal status because of the nature of their relationship. The recipient of the communication cannot be legally compelled to disclose it as a witness or voluntarily disclose it without the permission of the person making the disclosure. Privileged communications include those between husband and wife, attorney and client, physician and patient, priest and penitent, and so on.

Proximate cause: An act or omission that, unbroken by any intervening cause, produces an injury. In a medical malpractice case, failure to adhere to the standard of care must be the proximate cause of the injury to the patient.

Rebut: Refute; present opposing evidence or arguments.

Reservation of rights: An insurance term referring to situation in which a question arises about whether there is coverage for an incident.

Res ipsa loquitur: "The thing speaks for itself." A case in which the personal injuries or property damage would not have occurred without **negligence**. In medical malpractice cases, this theory allows a patient to prove his or her case without the need of an expert witness to testify that the defendant violated the **standard of care**. It is applicable only in those instances in which negligence is clear and obvious, even to a layman, such as in foreign object cases, when a surgeon leaves a sponge in the patient following surgery.

Respondeat superior: "Let the master answer." The legal principle that makes an employer liable for civil wrongs committed by employees within the course and scope of their employment.

Settlement: An agreement that resolves a legal dispute between the parties to a lawsuit.

Standard of care: A term used in the legal definition of medical malpractice. A physician is required to adhere to the standards of practice of reasonably competent physicians in the same or similar circumstances with comparable training and experience. National standard of care is a duty to exercise that degree of care and skill expected of a reasonably competent practitioner in the same specialty acting under similar circumstances.

Statute of limitations: The time period in which a plaintiff can file a lawsuit. Once this period expires, the plaintiff's lawsuit is barred if the defendant asserts the **jurisdictional defense** of the statute of limitations.

Statutory law: Laws enacted by a legislature.

Stipulation: An agreement made by both parties in litigation regulating any matter related to the case, proceeding, or trial. For instance, litigants can

agree to extend the time period for **pleadings** or to admit certain facts into evidence at the trial.

Structured settlement: Settlement agreement between the parties to a lawsuit or claim, in which the **damages** are paid to the plaintiff over time instead of in a lump sum. These settlements are usually financed through the purchase of an annuity.

Subpoena: Court order requiring a witness to appear at a certain proceeding to give testimony or produce documents.

Summary judgment: Granting of a judgment in favor of either party prior to trial. Summary judgment is granted only when there is no factual dispute and one of the parties is entitled to the **judgment** as a matter of law.

Summons: A legal document attached to the **complaint or declaration**. It orders the defendant or the defendant's attorney to file an **answer** within a specified period.

Timely: Promptly; within a reasonable period of time, with "reasonable" being judged in terms of the particular circumstances of a case.

Tort: A civil wrong for which an action can be filed in court to recover **damages** for personal injury or property damage resulting from negligent acts or intentional misconduct.

Trier of fact: The jury, or in the case of a trial without a jury, the judge.

Verdict: The formal decision or finding made by a jury or judge. The verdict is favor of the plaintiff or defendant, and **damages** can be awarded when the verdict is in favor of the plaintiff.

Vicarious liability: Civil liability for the torts of other. Physicians may be vicariously liable for the negligent acts of their employees committed within the scope of their employment (**respondeat superior**.) In a hospital setting, a surgeon may be vicariously liable for the negligent acts of all members of the surgical team (**captain of the ship**).

Work product: Materials used by an attorney in preparation for the litigation. These materials are not subject to **discovery**.

Wrongful birth: An action brought by parents who seek damages after the birth of an impaired child. The parents assert that they received inadequate medical care that led to the birth of the handicapped child and that if they had received proper genetic counseling or testing, the child's birth could have been prevented.

Wrongful conception/wrongful pregnancy: An action brought by parents who seek damages for a healthy but unplanned child born as a result of a failed sterilization, birth control, or abortion.

Wrongful life: An action brought by an impaired child who contends that if his or her parents had been correctly counseled about likely birth defects, he or she would have never been conceived or would have been aborted.