CHAPTER

8

LEGAL ISSUES AND FORMAL POLICIES

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The past decade has brought explosive growth in PACS technology, making large-scale teleradiology an integral part of many radiology practices. This reality has left legislatures, the courts, and a wide variety of organizations that formulate healthcare policy scrambling to keep pace with an ever-changing practice environment. The result is a patchwork of laws, court decisions, and formal policies formulated by the American College of Radiology (ACR) and others that address a wide variety of issues relating to teleradiology. Some issues, such as the medical licensure and institutional credentials necessary to practice teleradiology in a given jurisdiction, are fairly well defined. However, the majority of legal and policy issues that confront this increasingly important aspect of radiology practice are unsettled or not even addressed, leaving a broad range of unanswered questions. In addition to the challenges of addressing litigation and standards for the clinical aspects of radiology, the Health Insurance Portability and Accountability Act (HIPAA) has brought upon radiology a level of compliance complexity never seen before. The regulations penetrate every area of the department, and the policies further define and expand the obligations within

HealthCare Financing Administration (HCFA) regulations that were based on the Privacy Act of 1974.

THE CURRENT SITUATION

We are currently in the midst of an era of rapid technical innovation and change that is unequaled in recorded history. Computing power that required whole rooms a few short decades ago can now be conveniently carried. The cost of this computing power has fallen dramatically, making possible the widespread use of powerful computing platforms. The accompanying dramatic innovation in communications technology has allowed the inexpensive transfer of large volumes of data over long distances.

These innovations have combined to make teleradiology and picture archiving and communication systems (PACS) technology available in many medical settings. Digital images are acquired, transmitted, displayed, and stored in a wide variety of settings. These range from purely local exercises, such as the interpretation of computed tomography (CT) images at a scanner's dedicated workstation, to transmission of images over hundreds or thousands of miles for official interpretation and storage. The activities currently possible through available technology are in many ways limited only by the creativity of those who use it.

Like most activities with the potential to impact the health of the population, teleradiology and PACS technology are subject to controls established by the law and policies developed by various organizations. Laws enacted by Congress and by the various state legislatures are implemented by the executive branch through administrative agencies. These agencies draft regulations that define the day-to-day operation of the legislation, providing detail that is often absent from the law itself. The Food and Drug Administration (FDA) and the HCFA are well-known examples of federal agencies; a variety of state administrative agencies perform similar functions for state laws.

The content, meaning, or appropriateness of laws and regulations is often subject to dispute. Parties may contend that administrative agencies misinterpreted the law when drafting regulations, or perhaps overstepped the discretion that the law allowed them. In extreme cases, there may be questions as to whether Congress or the legislature possessed the authority to pass the law itself. In any such dispute, it is the courts at the federal, state, and local level that serve as the final arbiter of the law. In this role, they shape the final enforcement of any legislation.

Another source of control is policies, guidelines, and standards developed by private organizations with interests in a field. In teleradiology and PACS, the ACR has played a key role in developing standards for both the equipment employed and the role of radiologists and other personnel in applying the technology. While these standards lack the force of law, they serve an important function in defining teleradiology and PACS for those both in and outside the field of radiology. In this context, similar standards have been used by courts in examining disputes involving medical practice.

The various sources of law and policy do not ordinarily prospectively address issues. Typically, legislatures, administrative agencies, and professional organizations develop law and policy after problems have developed that demand resolution. This means that a conflict or problem must first occur and be identified before any action is taken.

Even when the need for a new law or policy is recognized, developing that law or policy is not a quick or easy process. Congress and the state legislatures may take years to draft and enact legislation, and administrative agencies years to define the new law with regulations. Courts may be even slower to resolve new legal problems, as a number of decisions on similar disputes are typically needed to form a body of law. Even professional organizations with vested interests in areas such as teleradiology and PACS, such as the ACR, generally have in place a complex mechanism to develop standards or guidelines, a process that may take years after the need for action is identified.

The result—in rapidly changing, technologically driven fields such as teleradiology and PACS—is a definite disparity between the capabilities of the technology and the institution of laws and policies to govern its use. Today, only a fraction of pertinent teleradiology and PACS issues have been addressed. Although almost every state has explicit or implied licensure requirements for radiologists interpreting teleradiology images from inside its borders, there is a dearth of court decisions addressing the various legal issues that are sure to affect its everyday practice. Furthermore, new laws are passed and new policies established on an ongoing basis, with the pace of these new controls bound to increase as the technology matures and its use becomes even more widespread.

This chapter outlines current law and policy as they pertain to teleradiology and PACS. It also outlines issues with the potential to affect the fields in the near future. It is not a substitute for qualified legal advice, and radiologists engaging in these activities are urged to consult qualified legal counsel before employing these technologies.

STANDARDS AND POLICIES OF PROFESSIONAL ORGANIZATIONS

The provision of medical services has been a long-standing focus of professional societies, and the activities made possible by the development of teleradiology and PACS technology are no exception. Given the technology's pronounced impact on the practice of radiology, the ACR has taken a leading role in defining what constitutes professionally acceptable teleradiology and PACS services, developing a variety of standards and other policies. The American Medical Association (AMA) has also examined the practice of teleradiology and telemedicine. The standards and policies developed by such organizations do not have the force of law, but they do represent a detailed consensus of expert opinion in the field. As such, they may serve as important indicators regarding what constitutes the professional standard of medical practice in teleradiology and PACS.

AMERICAN COLLEGE OF RADIOLOGY

The ACR is a leading professional society in radiology, with a membership composed of radiologists, radiation oncologists, and medical physicists. As part of an effort to advance the science of radiology and improve the quality of radiology services, the college has developed a formal mechanism for establishing and revising standards for the various subspecialty areas that make up the profession. Each standard represents a consensus policy statement by the college. Effective January 1, 1999, the ACR established new standards for teleradiology and digital image data management.

ACR STANDARD FOR TELERADIOLOGY

The ACR standard covers a wide variety of issues related to teleradiology. It stresses that teleradiology must be of sufficient quality to perform the indicated task. When a system is used to perform an official interpretation, there should not be a "clinically significant loss of spatial or contrast resolution from image acquisition through transmission to final image display." From this overriding principle, the document describes in detail the personnel and equipment considered necessary to conduct teleradiology.

Initially, the standard outlines the qualifications of personnel obtaining images at the transmitting site. These individuals must be qualified to

perform the specific examination being performed. In all cases, a licensed and/or registered radiologic technologist, nuclear medicine technologist, or sonography technologist is needed. In addition to appropriate technologists, a qualified medical physicist and an "image management specialist" are desirable to have on-site or as consultants. The document defines an image management specialist as an individual who is "qualified by virtue of education and experience" to provide service to the teleradiology system.

The physician performing the official interpretation of transmitted images must have a basic understanding of the strengths and weaknesses of teleradiology, as well as be qualified to interpret the particular diagnostic modality at issue. With regard to what constitutes adequate qualification, the standard refers to other ACR standards for rendering interpretations on the various imaging modalities. Notably, the teleradiology standard states that this physician should maintain licensure appropriate to the delivery of teleradiology services at both the transmitting and receiving sites. This effectively requires a physician interpreting teleradiology to maintain appropriate licensure in multiple states, if teleradiology is conducted across state lines and the state(s) involved require such licensure. The standard maintains a similar position on staff privileges: If images are transmitted from a hospital, the interpreting physician should be credentialed and obtain appropriate privileges at that institution.

Similar to legal requirements faced by physicians interpreting locally produced images, the ACR teleradiology standard holds the physician providing the official interpretation of teleradiology images responsible for the quality of the images being reviewed. Simply put, this position makes it difficult for physicians providing official teleradiology interpretation to escape potential liability for poor-quality images. Physicians providing official interpretations are also cautioned to consult with their professional liability carrier to ensure coverage in both sending and receiving sites. A large portion of the teleradiology standard addresses technical and legal issues associated with the equipment used and the images displayed and stored by that equipment. All new equipment acquisition should comply with the Digital Imaging and Communications in Medicine (DICOM) standard, developed by the ACR and the National Electrical Manufacturers Association (NEMA). Two matrix categories are established for rendering official image interpretation. A small matrix (512×512 resolution with a minimum of 8-bit depth) is deemed sufficient for computed tomography (CT), magnetic resonance imaging (MRI), ultrasound (US), nuclear medicine (NM), digital fluoroscopy, and digital angiography. Computed radiography and digitized radiographs are considered large-matrix studies (a minimum of 2.5 line pairs per millimeter [lp/mm] spatial resolution at a minimum of 10-bit depth).

Image data for teleradiology systems may be obtained by both direct image capture for purely digital images or by secondary image capture for film images that are digitized. Direct image capture is the "most desirable" method of acquisition for primary diagnosis. Regardless of acquisition method, images must have annotation capabilities that allow data such as patient name, identification number, name of transmitting facility, type of examination, anatomic orientation, and method of compression displayed on the image. The standard allows the use of both reversible and irreversible compression, assuming that a qualified supervising physician determines that there is no reduction in "clinically diagnostic image quality." These compression methods should be reviewed periodically by the supervising physician to "ensure appropriate image quality." Data transmission is required to have adequate error-checking capability, and there must be no loss of clinically significant data during this transmission.

Display characteristics for the monitors used in officially interpreting teleradiology images are described. These should have a luminance of at least 50 ft-lamberts and be located in areas with suitable room lighting. Image manipulation features should include window and level adjustments, pan and zoom, the capability to rotate or flip images, and the ability to calculate and display accurate linear measurements and pixel values (as appropriate for the modality being interpreted). The images should be accurately associated with the correct patient study and demographic information, and any compression or similar processing should be noted. Requirements for displays not being used for official interpretation are noted to be less stringent, though the exact characteristics are not delineated.

Archiving and retrieving image data receive significant attention in the standard. Prior examinations should be retrievable from the archive in a time frame appropriate to the clinical needs of the facility and medical staff. Any system should provide storage capable of complying with all facility, state, and federal regulations regarding medical record retention. Images stored at either the transmitting or receiving site should meet the specific jurisdictional requirements of the transmitting site. Images interpreted off-site need not be stored at the receiving facility. However, if such data are maintained at the receiving facility, the data retention period must meet the jurisdictional requirements of the receiving jurisdiction as well. All policies relating to the storage of image data should be written and equivalent to policies and procedures that exist for hardcopy medical images.

A teleradiology system should have protections to ensure the security of archived data. Specifically, the confidentiality of patient data must be addressed, as well as measures to safeguard the data from intentional or unintentional corruption. These protections should apply to both the network and the software it employs.

Finally, the standard addresses practical, day-to-day issues of teleradiology. Written policies and procedures to ensure a continuity of care consistent with that for hardcopy images are suggested. Mentioned are internal redundant systems, backup telecommunications links, and a disaster plan. At least monthly image quality control using a test image is described. Spatial resolution at such testing should be consistent with the specific matrix being employed, that is, small or large.

Currently, there is little indication as to how this revised teleradiology standard may be applied in practice. Given the ACR's reputation and the need for minimum standards in clinical teleradiology practice, many of the details of the standard will probably be adopted by radiologists practicing teleradiology. However, given the rapid advancement of technology, it is virtually certain that some of the standard's technical details will shortly be obsolete. The portions of the document calling for appropriate licensure in both the sending and receiving jurisdictions are likely to be considerably more enduring, as are the provisions applying to the archiving and retrieval of teleradiology data.

ACR STANDARD FOR DIGITAL IMAGE DATA MANAGEMENT

The ACR maintains a separate standard for digital image data management. Its provisions are applicable to any system of image data management, from single-modality or single-use system to a complete PACS system, as would be used for teleradiology. As a result, there is considerable overlap with the ACR Standard for Teleradiology, which focuses on PACS. Like the teleradiology standard, the digital image data management standard states that the examination that serves as the data source is subject to the specific ACR standard for that modality.

The goals of digital image data management as outlined in the standard include, but are not limited to: (1) initial acquisition or generation of accurately labeled and identified image data; (2) transmission of data to an appropriate storage medium from which they can be retrieved; (3) retrieval of data from available prior imaging studies for comparison; (4) transmission of data to remote sites for consultation, review, or formal interpretation; (5) appropriate compression of image data to facilitate transmission or storage, without loss of clinically significant information; (6) archiving of data to maintain accurate patient medical records in a form that is retrievable in a timely fashion, meets applicable facility, state, and federal regulations, and maintains patient confidentiality; and (7) administration with appropriate database management procedures.

Most of the document itself is devoted to describing in detail how these goals are to be accomplished. Qualifications and responsibilities for personnel, including physicians, electronic/computer assistant, medical image physicist, and image management specialists are outlined, largely paralleling descriptions in the teleradiology standard. Similarly, compliance with the DICOM standard is "strongly recommended," and image categories for official interpretation are split into those for small and large matrices. The definitions for these matrices and the type of imaging modalities in each type of matrix are identical to the teleradiology standard, as are the descriptions of image acquisition and annotation capabilities. Transmission standards likewise mirror those detailed in the teleradiology standard.

Archiving and retrieval sections of the digital image data management standard also reiterate those found in the teleradiology standard. Storage capacity must be capable of complying with all facility, state, and federal regulations regarding medical record retention, with images stored at either the transmitting or retrieval site complying with the requirements of the transmitting jurisdiction. Storage is not necessary at the receiving site, but if such storage is undertaken, the retention period of that jurisdiction must be met as well. Security to protect the confidentiality of patient identification and imaging data should be present. All policies relating to the achieving and storage of digital image data should be equivalent to those in existence for hardcopy records and should be in writing. For clinical use, any system must allow timely retrieval of archived images, as well as mechanisms to ensure continuity of care.

AMERICAN MEDICAL ASSOCIATION POLICIES ON TELEMEDICINE AND TELERADIOLOGY

The AMA is the largest medical professional society in the United States, encompassing the spectrum of medical specialties and issues. The growing importance of telemedicine, which includes teleradiology and PACS, has captured the association's attention at its highest levels. This has led to the issuance of several reports and implementation of certain policies.

In 1996, the AMA published "The Promotion of Quality Telemedicine," which was jointly issued by the Council on Medical Education and the Council on Medical Service. In this document, the AMA supports the ACR position that physicians providing "authenticated interpretation of images transmitted by teleradiology" should maintain licensure "appropriate to the delivery of radiologic service" at both the transmitting and receiv-

ing sites. As noted previously, this position generally requires that a radiologist interpreting telemedicine studies maintain full licensure in both the transmitting and the receiving jurisdictions. However, if the service provided is "curbside consultation," a phrase used to describe an informal second opinion where there is no expectation of compensation, the AMA policy recognizes that a full and unrestricted license is not needed.

AMA policy, however, does not recognize the ACR Teleradiology Standard and related standards as such. Under AMA policy for "practice parameters," as recognized in the AMA Policy for the Promotion of Telemedicine, such parameters serve as "educational tools" and "strategies for patient management that are designed to assist physicians in clinical decision making." This is distinct from the legal concept of a "standard of care," the level of medical care established necessary to defeat allegations of negligence in a malpractice action. Generally, this standard is established by physicians, testifying as experts as to the level of care required. Furthermore, a related policy states that "practice parameters developed by a particular medical specialty or specialties should not preclude the performance of the procedures or treatments addressed in that practice parameter by physicians who are not formally credentialed in that specialty or specialties." Thus, under existing AMA policy, ACR standards on teleradiology and digital image data management serve only an educational purpose and are not acknowledged to establish an actual standard of care.

The AMA has also tracked developments in telemedicine and teleradiology. In 1996, the House of Delegates, the AMA's governing body, adopted a resolution directing the association to monitor activities of hospitals, specialty societies, and regulatory agencies that affect telemedicine and submit a report. The result of this resolution was the Status Report of Telemedicine, issued at the 1997 interim meeting, a substantial portion of which outlined ACR actions in the area. ACR initiatives such as the DICOM standard, developed in conjunction with the NEMA, were acknowledged. The document also noted that the FDA Center for Devices and Radiological Health had encouraged such collaboration between the clinical community, as represented by the ACR, and manufacturers of diagnostic imaging equipment.

Given the growing importance of telemedicine in general and teleradiology in particular, there is little doubt that the AMA will continue to track developments and generate policy in the area. For the present, it is unlikely that the association will change its stance requiring full and unrestricted licensure in both transmitting and receiving jurisdictions in the setting of teleradiology, or acknowledge that ACR standards represent the professional standard of care.

GOVERNMENT REGULATIONS

Both the federal and state governments are involved in the regulation of teleradiology and PACS. This regulatory authority stems from legislation that controls medical devices, healthcare benefits, and the practice of medicine, with the regulations themselves drafted by a variety of administrative agencies. Generally, regulation at the federal level is directed at medical devices and the provision of healthcare benefits. At the state level, the dominant activity is regulation of medical practice.

FEDERAL GOVERNMENT

FOOD AND DRUG ADMINISTRATION

The FDA has its regulatory authority for medical devices grounded in the Food, Drug and Cosmetics Act, as amended by Medical Device Amendments of 1976 and other amendments, which requires that products be safe and effective for their marketed indication(s). The definition of a "medical device" under the act is extremely broad—broad enough to include devices employed for teleradiology and PACS. Devices regulated by the agency are broken down into several distinct groups. Initially, all devices are arbitrarily separated into those legally marketed prior to implementation of the Medical Device Amendments on May 28, 1976, and those marketed after that date. These are known as "pre-amendment" and "post-amendment" devices, respectively.

Pre-amendment devices are further divided into 3 classes, based on potential patient risk. Devices with the least risk are placed in class I, which is subject only to "general controls." Class I products are not individually regulated. Rather, their safety and effectiveness are assured by general controls, which include manufacturing and labeling controls. General controls are considered important for all medical devices. Accordingly, they also apply to class II and III products.

Class II is the intermediate regulatory category for devices with higher risk to patients than class I but not requiring the highest degree of regulation. Products in this class are subject to "special controls," specific regulations designed to assure their safety and effectiveness. As with class I, these devices are not individually regulated, with each generic product type subject to applicable special controls.

Class III is the most stringent regulatory category. It is reserved for products with either a potentially unreasonable risk of patient injury or with

insufficient data to establish actual patient risk. Devices in this class are technically subject to a premarket approval process, requiring demonstration of safety and effectiveness prior to marketing. However, pre-1976 class III products are "grandfathered" and may be legally marketed until such time as the FDA requests such data and the manufacturer either fails to provide them or the data fail to show safety and effectiveness.

Post-amendment devices are generally subject to a premarket notification process, which generally applies to higher-risk class II and all class III products. This requires that a manufacturer provide the FDA notice of its intention to market a product. If the agency determines that the product is "substantially equivalent" to a pre-amendment device (or a post-amendment device that has been reclassified to class I or II), that device may be legally marketed subject to the regulations currently applicable to its "predicate" device. Should there be no pre-1976 equivalent, the device is automatically placed in class III, subject to the premarket approval process. Lower-risk products may be reclassified to class I or II, although this generally requires evidence that the device's risk is appropriate to the new classification.

Teleradiology and PACS were not in existence in the pre-1976 world of medical devices. Though these post-amendment devices could have been automatically placed in class III, the FDA treated teleradiology and PACS equipment as accessories to the imaging devices that they serviced, avoiding the premarket approval process. However, this made marketing approval for the devices somewhat complicated, as the products were not themselves classified.

The FDA moved to end this system in 1996, issuing the policy statement "Telemedicine Related Activities." While reinforcing the agency's authority to regulate teleradiology and PACS devices, the statement proposed formally classifying the products. Image storage devices and medical image devices were to be placed in class I and exempted from the premarket notification requirement unless irreversible compression was used. Medical image digitizers, medical image hardcopy devices, and PACS systems were to be class II products. General purpose products used in a medical setting were not to be regulated, unless labeled for a medical use. The latter category could include such items as word-processing software employed in a PACS system.

The agency issued its final rule effecting these changes on April 29, 1998. As proposed in Teleradiology and Related Activities, these regulations placed medical image storage devices in class I, exempt from the premarket notification requirement unless irreversible compression is used. Medical image digitizers, medical image hardcopy devices, and PACS were made class II devices. A number of "voluntary standards" are to serve as special controls

for these devices: (1) DICOM; (2) Joint Photographic Experts Group (JPEG), which specifies methods for reversible and irreversible compression of digital medical images; and (3) the Society of Motion Picture and Television Engineers test pattern, used to test monitors and printers for acceptance and quality control purposes.

HEALTHCARE FINANCING ADMINISTRATION

The HCFA oversees the federal Medicare program, disbursing vast sums of money to healthcare providers and institutions nationwide. Given the scope of Medicare, HCFA regulations applicable to Medicare fund recipients have a broad impact on the provision of U.S. health care. HCFA itself is governed by the Privacy Act of 1974, a federal statute that protects the confidentiality of individually identifiable data. In practice, the act requires that HCFA keep the records of its Medicare patients confidential. HCFA is also subject to certain provisions of HIPAA, in which Congress mandated certain security and electronic signature requirements.

Recently, HCFA has become concerned that certain electronic data transmissions have the potential to violate patient confidentiality and hence the Privacy Act of 1974. Its response was the HCFA Internet Security Policy, issued in November 1998. This document applies to what HCFA describes as "HCFA Privacy Act-protected and/or sensitive HCFA information," which includes: (1) all individually identifiable data held in systems of records; (2) payment information that is used to authorize or make cash payments to individuals or organizations; (3) proprietary information that has value in and of itself and that must be protected from unauthorized disclosure; and (4) computerized correspondence and documents that are considered highly sensitive and/or critical to an organization and that must be protected from unauthorized alteration and/or premature disclosure.

The HCFA Internet Security Policy allows covered data to be transmitted via the Internet, as long as "an acceptable method of encryption" is utilized to provide confidentiality and integrity of the data. Furthermore, authentication or identification procedures must be employed to assure that both the sender and the recipient of the data are known to each other and are authorized to receive and decrypt such information. The policy covers all systems or processes that use the Internet or interface with the Internet to transmit sensitive data. However, it does not apply to local data-at-rest or local host or network protections, although it is explicit that such local data must still be protected by "all necessary measures."

The HCFA Internet Security Policy describes in considerable detail the technical specifications of acceptable practices. Minimally acceptable encryp-

tion methods as of November 1998 include algorithms such as Triple 56-bit DES (defined as 112-bit equivalent) for symmetric encryption, 1024-bit algorithms for asymmetric systems, and 160 bits for elliptical curve systems. The agency explicitly reserves the right to increase these minimum levels when "deemed necessary" by advances in techniques and capabilities associated with the processes used by attackers to break encryption.

Acceptable authentication approaches, accomplished over the Internet via an "in-band" process, include: (1) formal certificate authority-based use of digital certificates; (2) locally managed digital certificates, provided that all parties to the communication are covered by the certificates; (3) self-authentication, as in internal control of symmetric "private keys"; and (4) tokens or "smart cards." Acceptable identification approaches, undertaken outside the Internet via an "out-of-band" process, include: (1) telephonic identification of users and/or password exchange; (2) exchange of passwords and identities by U.S. certified mail; (3) exchange of passwords and identities by bonded messenger; (4) direct personal contact exchange of passwords and identities; and (5) tokens or smart cards.

Entities subject to the HCFA Internet Security Policy must modify their security plan to detail the methodologies and protective measures used if they employ the Internet for transmission of covered data and to adequately test these implemented measures. HCFA reserves the right to audit these organizations and their security policies. Finally, any organization wishing to transmit covered data via the Internet must inform HCFA of its intent to do so.

HCFA is in the midst of promulgating formal regulations addressing security of electronic individual healthcare information, as well as health plan use of electronic signatures.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT The passage of HIPAA has driven many to demand improvements in the management of the information systems within the healthcare system. When the Privacy Act of 1974 was passed, many saw the legislation as ineffective because it allowed the disclosure of the information without the subject's approval when the use of the information was routine. The rules that governed the definition of routine use were expanded, and the loopholes in the law continued to increase. Second, the burden of enforcement was placed entirely on the individual via the filing of a civil suit. However, the framework established by the Privacy Act of 1974 and HCFA have led to the development of a framework for HIPAA.

The Health Insurance Portability and Accountability Act is broken down into 3 principal rules:

- Transaction Rule: The facilitation of the exchange of information between providers and payers
- Privacy Rule: The empowerment of patients for access and control of their medical information
- Security Rule: The safeguards for the information exchanged in the transaction and privacy rules

Since computerized information systems drive almost every department within the hospital, the Security Rule will rely heavily on information technology to provide the required support to meet the other rules enforcement. Experts estimate that probably 10% or fewer of private healthcare organizations have adequate security; in other words, 90% or more have inadequate security. The implementation of security within a practice's information system is a complex process ranging from the establishment of dependable secure workflows of most departmental operations to the implementation of many new technical or operational changes to the existing information technology. The details regarding the implementation of policies and procedures to ensure HIPAA compliance are well beyond the scope of this book.

STATE GOVERNMENT

LICENSURE

At its most basic level, teleradiology is the practice of medicine. The right of the individual states to license such practice has been settled law in the United States since the turn of the century, when the U.S. Supreme Court upheld a West Virginia statute requiring that physicians practicing in that state obtain a license based on criteria established by the state (*Dent v. West Virginia*). Today, states enforce their licensure prerogative through medical practice statutes, which typically define what constitutes the "practice of medicine" and therefore who is subject to medical licensure. The definition of the practice of medicine is usually broad, as with North Carolina's statute:

any person shall be regarded as practicing medicine or surgery . . . who shall diagnose or attempt to diagnose, treat or attempt to treat, operate or attempt to operate

on, or prescribe for or administer to, or profess to treat any human ailment, physical or mental, or any physical injury to or deformity of another person

Although teleradiology is not specifically mentioned in this and other statutes, there is little doubt that the broad definition of medical practice encompasses the in-state teleradiology practitioner. The impact on out-of-state physicians who consult about patients located within the jurisdiction is less clear. To eliminate this confusion, many states have amended their medical practice statutes to clarify their applicability to out-of-state teleradiology practitioners (Goldberg and Gordon 1998). In states where statutes have not been altered, the impact on out-of-state practitioners remains uncertain.

Many states have various exceptions to their licensure requirement. For example, out-of-state physicians rendering emergency treatment are often exempt. "Occasional" consultants may be exempt, but the definition of what level of activity qualifies differs between states. Several states have "border states exceptions," which exempt licensed physicians in immediately neighboring states from the state's licensure requirement. Given the nature of teleradiology practice, with its typically nonemergent, recurrent nature and broad reach, it is likely that the applicability of all of these exemptions will be limited.

With current medical practice statutes and their exemptions, licensure requirements for out-of-state teleradiology practitioners fall into 1 of 3 general categories: (1) full licensure is either expressly required by statute or presumed because teleradiology and/or telemedicine is not specifically mentioned in the applicable medical practice act and no exemption applies; (2) a "special purpose" license for out-of-state teleradiology practitioners is available; and (3) full licensure is not required, though something short of full licensure may be necessary. The last 2 categories are infrequently encountered.

Given the potential consequences of violating medical practice statutes, it is advisable to exercise caution in all questionable practice situations. Loss of licensure in a practitioner's home state, exclusion from federal Medicare and Medicaid programs, and/or loss of malpractice insurance may all be indirect consequences of practicing without an appropriate license (California Business and Professions Code 1998a; 42 USCA. 1998; NORCAL Mutual Insurance Co. 1997). Interestingly, violation of the medical practice statute itself is typically only a misdemeanor (California Business and Professions Code 1998b).

Licensure requirements, current as of April 1999, for the 50 states appear in Table 8.1. Also included are pertinent, specific state requirements.

TABLE 8.1
Licensure Requirements (1999)

State	Code	Specific Requirements
Alabama	3	Grants a 3-year special-purpose license to nonresident telemedicine practitioners. Excludes informal or uncompensated consultations. Subjects licensee to Alabama medical board jurisdiction and requires licensee's home state to issue reciprocal telemedicine licenses to Alabama physicians.
Alaska	1	
Arizona	2	"Single or infrequent" consultations are exempted.
Arkansas	2	Episodic consultations with Arkansas physicians, provision of services unavailable in Arkansas, or physical travel to the state to provide care are exempted.
California	3	No license required so long as the telemedicine consultant does not have ultimate authority over the patient; requires specific informed consent from the patient to use telemedicine consultation; exempts telephone conversations and e-mail messages between patient and practitioner.
Colorado	2	"Occasional" consultations exempted.
Connecticut	2	"Occasional" consultations exempted.
Delaware	1	
District of Columbia	1	
Florida	2	Full licensure for physicians providing official authenticated interpretations through an ongoing regular arrangement.
Georgia	2	
Hawaii	3	Telepractitioners exempted from licensure if local physician maintains primary control over the patient's care.
Idaho	2	
Illinois	2	Out-of-state physicians practicing telemedicine subject themselves to the jurisdiction of Illinois courts.
Indiana	2	Full licensure for telemedicine on a regular routine or nonepisodic basis.
Iowa	1	
Kansas	2	Exemption for occasional consultation; border states exemption.

TABLE 8.1
Continued

State	Code	Specific Requirements
Kentucky	1	
Louisiana	1	No consultation exception.
Maine	1	No consultation exception.
Maryland	1	
Massachusetts	1	Opinion of medical board attorney that full licensure needed.
Michigan	1	
Minnesota	1	
Mississippi	2	Exemption if local physician requests nonresident physician's services. The resident physician must have a prior relationship with the patient being treated via telemedicine.
Missouri	2	Exemption when consulting with local physician.
Montana	3	A bill pending in the legislature would require a telemedicine certificate issued by the medical board; passed House, pending in Senate as of 2/22/99.
Nebraska	2	
Nevada	2	
New Hampshire	1	Bill pending in legislature to explicitly require full licensure for physicians who provide teleradiology services on a regular contractual or frequent basis.
New Jersey	1	
New Mexico	1	
New York	1	Border states exception.
North Carolina	2	Exemption for infrequent consultations. Residents may bring malpractice claims against telemedicine practitioners in North Carolina courts.
North Dakota	1	Bill pending in legislature to require full licensure.
Ohio	1	
Oklahoma	2	Brief consultation exception; telemedicine practitioners submit to the jurisdiction of Oklahoma courts.

TABLE 8.1
Licensure Requirements (1999) *(Continued)*

State	Code	Specific Requirements
Oregon	1	Bill pending in legislature to require a special telemedicine license that is not a limited license but still does not allow the out-of-state physician to practice in the state, except across state lines.
Pennsylvania	1	
Rhode Island	1	
South Carolina	1	
South Dakota	2	Consultation exception limited to maximum 24-hour period in any 1 year.
Tennessee	2	On 5/15/96 the medical board was authorized by the legislature to issue special telemedicine licenses; as of 2/25/99 there is a bill pending in the legislature that would make transmission of patient medical information via telemedicine technology to a person in another state who is not licensed in Tennessee grounds for license suspension or revocation.
Texas	3	The state board of medical examiners is authorized to issue special-purpose licenses for telemedicine; otherwise, full licensure required.
Utah	2	Consultation exception repealed.
Vermont	1	Bill pending to authorize special-purpose license.
Virginia	1	
Washington	1	Bill pending that would require telemedicine practitioner to be sponsored by a local physician.
West Virginia	2	Consultation exception provides that consultant cannot consult for more than 3 months in his lifetime.
Wisconsin	1	
Wyoming	1	

Key: 1: States that have not specifically addressed the telemedicine licensure issue, so that full licensure is presumed.
2: States that specifically include telemedicine in their definition of medical practice and expressly require full licensure.
3: States requiring something other than full licensure, such as a special-purpose license or no license in the state.

Given the myriad of state licensure requirements, some have advocated a more uniform system of licensure for telemedicine/teleradiology. In 1996, the Federation of State Medical Boards suggested that the states adopt limited telemedicine licenses. However, leading national medical organizations, such as the ACR and the AMA, have adopted policies advocating full licensure in each state where a physician practices teleradiology. The states themselves heavily favor full licensure for physicians treating patients within their borders and appear extremely reluctant to surrender any authority to regulate such medical care. In this current climate, it is unlikely that any type of national licensure for teleradiology practice will emerge in the foreseeable future.

OTHER STATE ISSUES

In addition to licensure, many states have enacted legislation that affects teleradiology. Generally, these laws and regulations address teleradiology/telemedicine initiatives within the state, or attempt to coordinate such activities to achieve a public health goal. For example, some states are actively promoting telemedicine to provide care to their rural populations. A complete description of these nonlicensure activities is beyond the scope of this discussion.

RELATED LEGAL CONSIDERATIONS

The practice of teleradiology and PACS storage of image data raise a number of legal concerns, mostly related to state law doctrines. These include medical malpractice and record-keeping issues. To date, there are no cases known to the authors or other commentators directly addressing teleradiology and PACS (Caryl 1998). Accordingly, most analysis in this area is by analogy to conceptually similar fact situations.

MEDICAL MALPRACTICE IN TELERADIOLOGY

ESTABLISHING A CLAIM

Teleradiology is medical practice and, as such, exposes a physician to liability under state tort law, commonly known as medical malpractice. Successful malpractice actions require 4 elements: (1) a duty to the patient; (2) a

negligent breach or violation of that duty; (3) patient injury as a result of that negligence; and (4) actual damages from the injury. Assuming that a patient has suffered injury that has resulted in damages, as is the case in most malpractice actions, the question becomes whether the teleradiology practitioner owes a duty to the patient whose images he or she interprets and what constitutes negligence in that interpretation.

There is no definitive case law addressing the existence of duty owed to a patient by a teleradiology practitioner. However, most commentators believe that a doctor-patient relationship exists between a radiologist interpreting teleradiology images and the patient whose images he or she reviews, a relationship that establishes a duty to that patient (Caryl 1998; Cuzmanes and Orlando 1997). A court decision supporting this proposition is *Hand v. Tavera* (1993), in which a physician under a managed care contract who refused to hospitalize a patient was held to have formed a doctor-patient relationship, despite the fact that he had never met or spoken with that patient. The court reasoned that the relationship was established as the patient had paid for the physician's services. Another decision is *McKinney v. Schlatter* (1997), which found that a telephone consultation is sufficient to establish a doctor-patient relationship, when a physician relied on a cardiologist's advice that a clinical problem was not cardiac in nature. Given that a teleradiology practitioner is paid for his or her interpretation, and that interpretation is ordinarily relied on to guide clinical decision making, these cases indicate that typical teleradiology consultations will be sufficient to establish a duty to the patient.

It is less clear that a doctor-patient relationship is established when the consultation is informal, no compensation is received, and no official interpretation is rendered. Specifically, if the teleradiology practitioner is engaged in a "curbside consult," there is the possibility that no relationship will be found (Berger and Cepelewicz 1996). However, if the radiologist receives or expects any compensation from the consult, it is doubtful that any "curbside consult" exception would apply.

A second key requirement of a successful malpractice action is negligent breach of a physician's duty to the patient. Negligence exists when a physician has violated the medical standard of care, a legal concept whose exact definition varies among jurisdictions. Generally, this standard is established by physicians, testifying as experts, as to what constitutes acceptable medical practice in the fact situation before the court. Although these standards were originally based on practice patterns in the local community where injury occurred, there has been a growing trend in medical malpractice to a national standard of care, applicable across jurisdictions. Teleradiology, with its wide geographic sweep and cross-jurisdictional nature, will

almost certainly involve a national standard of care. The exact form this standard takes will depend on case law developed as malpractice cases involving teleradiology inevitably come before the courts.

CHOICE OF LAW

Medical malpractice is a legal action based in state law—law that may differ greatly among jurisdictions. These differences become problematic when the teleradiology practitioner interprets images of a patient who resides in and was imaged in another state. Here, the question becomes which law, that of the transmitting state or that of the receiving state, to apply.

Although teleradiology and PACS are new technologies, the choice of which state law to apply when a plaintiff and defendant are residents of different jurisdictions is not new for the courts. Under well-established law, a state may exercise jurisdiction on an out-of-state individual or corporation provided that there are "minimum contacts" between the state and the individual or corporation (*International Shoe v. Washington* 1945). Three criteria must be met: (1) the defendant must have purposefully availed him- or herself of acting in the state; (2) the cause of action must have arisen in the state; and (3) the defendant's acts must have a substantial enough connection to make exercise of jurisdiction reasonable (*Compuserve, Inc. v. Patterson* 1996). In the setting of commercial activity, it is widely acknowledged that committing an act of negligence in a state or doing business in that jurisdiction satisfies these requirements. Commentators examining teleradiology believe that this doctrine will be used to subject practitioners to the laws of the transmitting jurisdiction, although in the absence of applicable court decisions, the question remains unresolved (Caryl 1998). Some states have acted to remove this uncertainty by enacting legislation that specifically subjects out-of-state telemedicine practitioners to the state's jurisdiction.

The practical implications of a teleradiology practitioner being subject to the laws of the transmitting jurisdiction may be profound. A radiologist could find him- or herself facing a local judge or jury potentially hostile to an out-of-state defendant. Perhaps even more important, applicability of another state's jurisdiction may destroy protections a physician enjoys in his or her home state, such as award limits on the amount of allowable damages.

INSURANCE ISSUES

Interstate teleradiology practice raises professional liability insurance coverage issues related to the interpretation of images generated outside the prac-

titioner's home state. Coverage of out-of-state teleradiology activities should not be presumed. Not all insurance carriers are licensed in every state, and underwriting criteria among jurisdictions may vary. Accordingly, many policies specifically exclude coverage for out-of-state incidents, unless a rider has been added to specifically provide such coverage. This means that the unwary teleradiology practitioner subject to an out-of-state malpractice action may find his professional liability carrier reserving coverage rights or completely denying coverage.

RECORD KEEPING

Data generated from teleradiology and PACS activities are medical records. As such, there are a myriad of considerations regarding data storage, including where the data must be maintained, their form, and the period of retention. Confidentiality of data is another consideration. Laws, regulations, and institutions' policies for film and paper records may serve as a guide, though the vary nature of electronic data will necessarily demand special considerations.

Initially, when electronic data are acquired at one site and stored at another, it is unclear whether these data must be maintained at the transmitting site, the receiving site, or both sites. As discussed previously, the ACR Standard for Teleradiology requires only that data be maintained at the transmitting site. Certainly, any applicable law, regulation, or institutional policy with regard to where data must be maintained should be observed.

The form of stored image data is another consideration. Given the present cost of electronic storage and the amount of that storage necessary to archive medical images, many centers compress data to save resources. If compression is reversible, there is no intrinsic problem. However, when irreversible, "lossy" compression is employed, there is a question of a medical record being altered and clinically relevant data being lost. In the somewhat analogous setting of hardcopy medical records, any alteration may be extremely problematic legally, as it calls into question the validity of the entire record (Andrews 1992). It remains to be seen whether storage with lossy compression practice will become an issue for the courts.

The retention period of medical records is subject to federal, state, and institutional laws and policies. Laws and policies for the jurisdiction where electronic data are being stored should be followed. In addition, the ACR Standard for Teleradiology suggests that teleradiology data being stored at the receiving facility meet the storage standards at the transmitting facility.

This policy is prudent, given the probable applicability of the transmitting state's laws to the teleradiology practitioner.

A final consideration with any stored medical record is confidentiality. Various authorities, the physician/patient privilege, ethical considerations, the constitutional right to privacy, and some state statutory law demand that this confidentiality be maintained (Andrews 1992). Although electronic storage may be a more convenient and accessible format for storing and accessing medical records, this form of record keeping may be more vulnerable to security breaches.

As described in the ACR Teleradiology Standard and the ACR Standard for Digital Image Data Management, security is needed for electronically stored medical records. The ACR standards notwithstanding, there is virtual certainty that the courts would apply the same privacy standards to electronic records that have been applied to traditional medical records (*Alberts v. Devine* 1985). This imposes a duty on the physicians and institutions using teleradiology and PACS to develop policies that assure reasonable patient confidentiality, or face potential liability for breaches of confidentiality.

CONCLUSION

Teleradiology and PACS technology and application have expanded greatly in the last decade, in many ways leaving behind the laws and policies intended to regulate and control the field. Even where policies have been developed, such as the ACR Standard for Teleradiology and the ACR Standard for Digital Image Data Management, it is unclear what impact these policies will have on the practice of teleradiology and the use of PACS. Many of the legal and policies questions being asked by radiologists and others today will not be answered for years, as legislatures, courts, and professional societies develop approaches to the novel problems posed by the technology. Until that time, physicians using teleradiology and PACS technology should use caution and common sense when confronted with unsettled legal or regulatory questions.

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