

Chapter 40

Telemedicine and Electronic Mail Communication with Patients

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Telemedicine
Legal Issues

Conclusion

TELEMEDICINE

Telemedicine is specifically defined as the application of telecommunications to the care of the individual.¹ However, in general medical parlance, the terms “telemedicine” and “telehealth” have come to mean the convergence of the burgeoning technology of the telecommunications industry and the health care professions. Reduced to its simplest terms, telemedicine is nothing more than the electronic transfer of health care information from one site to another.² Telemedicine can probably trace its historic roots back to the Civil War when Union Army physicians telegraphed for medical supplies. However, the term “telemedicine” was introduced almost 40 years ago when the Bureau of Indian Affairs used telephone and video programs to train paramedics on the reservations. Today, the status of telemedicine far exceeds the expectations one arouses with a statement about its origins or the simple transfer of data.

Probably nothing has contributed to the advances in telemedicine more than digital imaging. Digital photographs work with light sensitivity just like standard film photography does. However, in digital imaging the image is captured on a chip instead of on film and the digital image can capture approximately 16 million colors and 250 shades of gray. When digital imaging is coupled with image enhancement, the electronic image produced can be clearer and sharper than what the on-site observer can visualize with the unaided eye. In addition to digital imaging, the development of fiber optic transmission and data compression techniques has aided the speed of transmission and helped prevent contamination of the signals. Virtual reality techniques have added the possibility of a three-dimensional image evaluation, and satellite transmissions have added an international and intercontinental and even an interplanetary scope to telemedicine.³ Now, streaming video and broadband connectivity have improved video teleconferencing and further enhanced telemedical practice.

The term “telemedicine” is currently used to cover a wide variety of health applications, and more are developing rapidly. It is estimated that by the turn of the next century the majority of American physicians will be involved with telemedicine in some way.

E-Mail and Physician–Patient Communication

Electronic mail (e-mail) occupies a singular position in health care law. Because of its unique properties it is part of telemedicine law, part of medical records law, has many of the legal attributes of the telephone in health care law, and mimics the evidence problems of traditional mail. Access to the Internet through an Internet service provider (ISP) and transmission from one user to another via the Internet is by far the fastest growing means of communication worldwide. The speed, ease, and low cost of sending information over the Internet has made it the communication media of choice of industry, and commerce, and it is rapidly becoming the patient’s method of accessing health care information.

E-mail is particularly well suited to transmit to the patient anything the patient would have to write out if it were transmitted orally. E-mail also provides a ready-made permanent record that has the capability of being printed out to become part of a patient’s paper medical record or being exported electronically to the patient’s electronic medical record without manual recopying. The message may also be forwarded to other interested parties without retyping. Because it is essentially a typed message, illegible messages are eliminated. Finally, e-mail allows embedded links to recommended or appropriate educational sites on the web.

E-mail has taken on a distinctive role in physician–patient communications. With the expanding use of computers by the public, the majority of patients now have access to e-mail. Among the various physician–patient interactions via e-mail that have been advocated or adopted are the following: postoperative checks on patients; giving directions and educational materials to patients; answering prescription refill requests; appointment requests, reminders, and changes; receiving and answering referral requests; receiving and answering medication questions; reporting adverse drug reactions; transmitting laboratory and diagnostic test results to the patient; exchanging insurance information; reporting home-generated results (glucose levels, urine volumes, blood pressures, etc.); and even get well cards or birthday greetings. In addition, e-mail allows

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the physician to send out a series of standardized letters to both patients and colleagues such as thank you letters for referrals, notices of office hour changes, holiday greetings and closures, changes in coverage, new phone numbers, and a myriad of similar notifications.

E-mail resembles a postcard rather than a letter. It is open to its carrier or carriers. The message is sent through many connections and networks during transmission. The message is usually fragmented and, while it is theoretically possible for it to be seized and read anywhere in the milliseconds along the way, its practical vulnerability lies in the ISP or ISPs of the sender and the recipient and upon the desktop of the sender and recipient. There it is intact and stored and may be easily and legally accessed by ISP personnel, office personnel, family members, or third parties able to access an unattended computer terminal. At these points it is most vulnerable to hackers. Personal information may be read, copied, altered, or forwarded without the sender or recipient ever knowing of the intrusion. E-mail is infinitely easier to forge than is regular mail. There is no handwriting or scripted signature to compare, and rare type fonts and graphic identifiers may be readily scanned and duplicated on a computer.

Encryption and the use of secure servers truly enhance security. Both encryption and secure messaging services have been touted as necessary to satisfy the Department of Health and Human Services Standards for Privacy of Individually Identifiable Health Information,⁴ the final regulations for which were published in 2002.⁵ Based on these relaxed final rules and the Department of Health and Human Services discussion of the rules,⁶ it would appear that with proper consent unencrypted messages may be sent through regular ISPs. In addition, it is inherently easier to send material to the wrong address in e-mail than with regular mail. To send an e-mail, the sender usually clicks on a name on a list and the letter is automatically addressed. All computer users have experienced the frustration of discovering that the cursor was one line up or one line down from the intended item on a menu. Therefore, e-mail is more frequently misaddressed than is regular mail. The "Reply to All" or "List Send" can also create a problem by revealing the name of every patient to every other patient. Eli Lilly have settled a case based on this very happening.⁷ (Because Eli Lilly was not considered a health care provider, the case was brought by the FTC and not under the Health Insurance Portability and Accountability Act (HIPAA)). The recipient, with little more than the push of a button, may forward the message to any individual or individuals anywhere in the world without recopying or securing the sender's permission. Another potential problem results from the fact that ISPs routinely make backup copies of all messages. These backup copies may remain in the system long after the message has been erased from both the sender's and recipient's memories and computers.⁸ Finally, there is a measure of social inequality in the distribution of e-mail capability. E-mail service is directly correlated to income and distributed unevenly across racial and ethnic groups.⁹

American Medical Informatics Association (AMIA) Guidelines

In 1997, the AMIA adopted the guidelines proposed by their task force on clinical use of electronic mail with patients. This was published as their White Paper, *Guidelines for the Clinical Use of Electronic Mail with Patients*.¹⁰ The guidelines were presented in a dual approach, guidelines for effective communication with patients and risk management or medical-legal guidelines. Unfortunately, these guidelines do not satisfy many legal commentators, and several alternative sets of guidelines have been published or generally outlined in law review articles.¹¹

Defining a turnaround time is essential for successful e-mail communication. One of the essentials is to be conservative in stating a turnaround time. If there is a chance that on busy days the e-mail will only be checked once per day, it is important that the provider not warrant that it will be checked more often than that. The AMIA guidelines envisioned a 2- to 3-day turnaround time for e-mail. Present practice would indicate that e-mail has attained a next-day turnaround in most offices, and in many offices messages received during one business day are processed that day. AMIA guidelines ask for provider assurances of privacy and security in multiple guidelines. The current thought is described above; there is a reasonable expectation of privacy on e-mail but the provider has no control of the security and/or the integrity of the e-mail communication and should make no assurances as to confidentiality or integrity or distinguish degrees of sensitivity of messages. The remainder of the communication guidelines are as valid today as they were in 1997.

Unfortunately the medical-legal guidelines have not fared as well in the ensuing years. Certainly an informed consent and e-mail practice policies are as important today as then, but the recommended content of those documents has changed with time. Today the consent form must conform to the consent requirements of DHHS's Standards for Privacy of Identifiable Health Information.¹² The essence of the informed consent agreement still should be that the provider is making no assurances of e-mail confidentiality or security and that the patient desires that the communications of the types enumerated be communicated by e-mail. The consent should also carefully, and conspicuously, detail whether or not the e-mail messages will be encrypted. Certainly the fact that the provider will make the e-mail transmission part of the written or electronic medical record is still an essential part of the consent but, in these days of multiple providers and shifting personnel, the hours of e-mail service are more important to detail than trying to detail who will service the communication.

CME and Administrative Conferences

Today, telemedicine is commonly utilized by large health provider organizations to communicate over an intraorganizational network. Large clinics or hospitals can hold administrative or business meetings with their outlying or rural clinics or branches via videoconference. These video

conferences can be as effective as face-to-face meetings and have the advantage of saving the time and expense of transporting personnel between facilities. The Accreditation Council for Continuing Medical Education (ACCME) is an organization whose mission is the identification, development, and promotion of standards for quality continuing medical education (CME) utilized by physicians in their maintenance of competence and incorporation of new knowledge to improve quality medical care for patients and their

communities. This organization fulfills its mission through a voluntary self-regulated system for accrediting CME providers and a peer-review process responsive to changes in medical education and the health care delivery system.

Live or enduring material activities that are provided via the Internet, now known as "Internet CME," must comply with all ACCME Essential Areas and Elements (Box 40-1), including the Standards for Commercial Support (Box 40-2) for proper accreditation. Because of the special nature of

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Box 40-1. ACCME Essential Areas and Elements

ELEMENT 1.1: MISSION

The provider must have a written statement of its CME mission, which includes the CME purpose, content areas, target audience, type of activities provided, and expected results of the program.

Non-Compliance:

Has no mission statement

Partial Compliance:

Has a mission statement, but omits one or more of the basic components.

Compliance:

Has a mission statement that includes all of the basic components.

Exemplary Compliance:

Has a mission statement that includes all of the basic components with a strong emphasis on assessment of results.

ELEMENT 1.2: PARENT ORGANIZATION

The provider must demonstrate how the CME mission is congruent with and supported by the mission of the parent organization, if a parent organization exists.

Non-Compliance:

CME not mentioned in the parent organization mission statement and no support provided.

Partial Compliance:

CME mentioned in the parent organization mission statement but no support provided, or CME not mentioned in the parent organization mission statement but support provided.

Compliance:

CME mentioned in the parent organization mission statement and supported with financial, facility, and human resources; or a CME mission statement reviewed and approved by the governing body of the parent organization on a regular basis.

Exemplary Compliance:

CME mentioned in the parent organization mission statement and supported with financial, facility, and human resources, plus promotion of the function; and a CME mission statement that is reviewed, evaluated, and approved by the governing body of the parent organization on a regular basis.

ELEMENT 2.1: PLANNING PROCESSES

The provider must use a planning process(es) that links identified educational needs with a desired result in its provision of all CME activities.

Non-Compliance:

Planning process(es) not used.

Partial Compliance:

Planning process(es) used inconsistently or does not reflect a link between identified educational needs and desired result.

Compliance:

Planning process(es) used consistently that link(s) identified educational needs and desired result.

Exemplary Compliance:

Innovative and creative planning process(es) used consistently, with documentation that identified educational needs contribute to appropriate methodology and desired results for the offered activities.

ELEMENT 2.2: NEEDS ASSESSMENT

The provider must use needs assessment data to plan CME activities.

Non-Compliance:

Needs assessment data are not used.

Partial Compliance:

Needs assessment data are not consistently used.

Compliance:

Needs assessment data are consistently used.

Exemplary Compliance:

Needs assessment data from multiple sources are consistently used to plan and evaluate activities.

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Box 40-1. ACCME Essential Areas and Elements—cont'd

ELEMENT 2.3: PURPOSE AND OBJECTIVES

The provider must communicate the purpose or objectives of the activity so the learner is informed before participating in the activity.

Non-Compliance:

Purpose or objectives of the activity are not communicated to the learner.

Partial Compliance:

Purpose or objectives of the activity are inconsistently communicated to the learner.

Compliance:

Purpose or objectives of the activity are consistently communicated to the learner.

Exemplary Compliance:

Purpose or objectives of the activity describe learning outcomes in terms of physician performance or patient health and are consistently communicated to the learner.

ELEMENT 2.4: ACTIVITY EVALUATION

The provider must evaluate the effectiveness of its CME activities in meeting identified educational needs.

Non-Compliance:

Educational activities are not evaluated.

Partial Compliance:

Educational activities are evaluated inconsistently and/or documentation is inconsistent.

Compliance:

Educational activities are evaluated consistently for effectiveness in meeting identified educational needs, as measured by satisfaction, knowledge, or skills.

Exemplary Compliance:

Educational activities are evaluated consistently for effectiveness in meeting identified educational needs, as measured by practice application and/or health status improvement.

ELEMENT 2.5: PROGRAM EVALUATION

The provider must evaluate the effectiveness of its overall CME program and make improvements to the program.

Non-Compliance:

No mechanism in place to measure the program's effectiveness or make improvements.

Partial Compliance:

Mechanism in place to measure the effectiveness of the program, but no documentation exists that the mechanism has been used or any changes have resulted from the process.

Compliance:

Mechanism in place to measure the effectiveness of the program, with evidence that improvements have been made.

Exemplary Compliance:

Innovative and creative mechanism(s) in place to measure the effectiveness of the program with evidence of improvements being made on a regular basis.

ELEMENT 3.1: ORGANIZATIONAL FRAMEWORK

The provider must have an organizational framework for the CME unit that provides the necessary resources to support its mission including support by the parent organization, if a parent organization exists.

Non-Compliance:

Organizational framework does not exist for the CME unit.

Partial Compliance:

Organizational framework does exist for the CME unit but not all components of the Element (resources and support) are present.

Compliance:

Organizational framework for the CME unit exists and all the components of the Element (resources and support) are present.

Exemplary Compliance:

Organizational framework for the CME unit exists, all components of the Element (resources and support) are present including a process to review and continually improve the organizational framework.

ELEMENT 3.2: BUSINESS AND MANAGEMENT PRACTICES

The provider must operate the business and management policies and procedures of its CME program (as they relate to human resources, financial affairs and legal obligations), so that its obligations and commitments are met.

Non-Compliance:

Business and management policies and procedures (as they relate to human resources, financial affairs and legal obligations) are not in place or the provider does not meet its obligations and commitments under these policies and procedures.

Partial Compliance:

Not Available Option

Compliance:

Business and management policies and procedures (as they relate to human resources, financial affairs and legal obligations) are in place and are used by CME administration to meet its obligations and commitments.

Exemplary Compliance:

Innovative and creative business and management policies and procedures (as they relate to human resources, financial affairs and legal obligations) are in place to assist the CME administration in meeting its obligations and commitments.

Box 40-1. ACCME Essential Areas and Elements—cont'd

ELEMENT 3.3: DISCLOSURE AND COMMERCIAL SUPPORT

The provider must present CME activities in compliance with ACCME's policies for disclosure and commercial support.

Note: The ACCME's policies for disclosure and commercial support are articulated in: (1) The Standards For Commercial Support: Standards to Ensure Independence in CME Activities, as adopted by ACCME in September 2004; and (2) ACCME policies applicable to commercial support and disclosure. All materials can be found on www.accme.org.

Non-Compliance:

The Provider

Does not ensure independence in planning CME activities (SCS 1), or
Does not have a mechanism to identify and resolve conflicts of interest (SCS 2), or
Does not appropriately use commercial support (SCS 3), or
Does not appropriately manage commercial promotion (SCS 4), or
Does not present content without commercial bias (SCS 5), or
Does not disclose required information (SCS 6).

Partial Compliance:

Not Available Option

Compliance:

The Provider

Ensures independence in planning CME activities (SCS 1), and
Implements a mechanism to identify and resolve conflicts of interest (SCS 2), and
Uses commercial support appropriately (SCS 3), and
Manages commercial promotion appropriately (SCS 4), and
Presents content that is without commercial bias (SCS 5), and
Discloses required information (SCS 6).

Exemplary Compliance:

Provider is compliant with all aspects of ACCME's policies on disclosure and commercial support and has implemented a range of innovative and creative practices.

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Box 40-2. ACCME Standards for Commercial Support

Standards to Ensure Independence in CME Activities

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a "commercial interest" as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.

- (a) Identification of CME needs;
- (b) Determination of educational objectives;
- (c) Selection and presentation of content;
- (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
- (e) Selection of educational methods;
- (f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or

responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

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Box 40-2. ACCME Standards for Commercial Support—cont'd**Standards to Ensure Independence in CME Activities***Expenditures for an individual providing CME*

- 3.7** The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.
- 3.8** The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.
- 3.9** No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.
- 3.10** If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

- 3.11** Social events or meals at CME activities cannot compete with or take precedence over the educational events.
- 3.12** The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

- 3.13** The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

STANDARD 4: Appropriate Management of Associated Commercial Promotion

- 4.1** Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.
- 4.2** Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.
 - For *print*, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.
 - For *computer based*, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer "windows" or screens of the CME content

- For *audio and video recording*, advertisements and promotional materials will not be included within the CME. There will be no "commercial breaks."
- For *live, face-to-face CME*, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.
- 4.3** Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.
- 4.4** Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.
- 4.5** A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

STANDARD 5: Content and Format without Commercial Bias

- 5.1** The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
- 5.2** Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

STANDARD 6: Disclosures Relevant to Potential Commercial Bias*Relevant financial relationships of those with control over CME content*

- 6.1** An individual must disclose to learners any relevant financial relationship(s), to include the following information:
 - The name of the individual;
 - The name of the commercial interest(s);
 - The nature of the relationship the person has with each commercial interest.
- 6.2** For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity

- 6.3** The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.
- 6.4** "Disclosure" must never include the use of a trade name or a product-group message.

Timing of disclosure

- 6.5** A provider must disclose the above information to learners prior to the beginning of the educational activity.

these activities, the ACCME governs the following specific aspects of these CME programs:

- **Activity location.** ACCME accredited providers may not place their CME activities on a pharmaceutical or device manufacturers' product website.
- **Links to product websites.** With clear notification that the learner is leaving the educational website, links from the website of an ACCME accredited provider to pharmaceutical and device manufacturers' product websites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity.
- **Advertising.** Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer-based CME activities, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer "windows" or screens of the CME content.
- **Hardware/software requirements.** The accredited provider must indicate, at the start of each Internet CME activity, the hardware and software required for the learner to participate.
- **Provider contact information.** The accredited provider must have a mechanism in place for the learner to be able to contact the provider if there are questions about the Internet CME activity.
- **Policy on privacy and confidentiality.** The accredited provider must have, adhere to, and inform the learner about its policy on privacy and confidentiality that relates to the CME activities it provides on the Internet.
- **Copyright.** The accredited provider must be able to document that it owns the copyright for, or has received permissions for use of, or is otherwise permitted to use copyrighted materials within a CME activity on the Internet.

Teleradiology

Radiology was the first of the clinical specialties to realize the potential of telemedicine. Remote interpretation of medical imaging is now an established medical procedure. The American College of Radiology has established medical standards as to the qualifications, credentialing, equipment, and quality assurance necessary for telemedicine. Not only can the images be transmitted by digital graphic techniques, but those same techniques are making it possible to save the huge areas of space formerly devoted to the storage of x-ray films. No longer must a rural or outlying physician suffer for the lack of a radiologist to read an emergency film. The image can be transferred to an on-call radiologist digitally and electronically in minutes. In addition, valuable radiology oncology information may be exchanged rapidly between the radiation physicist, the radiology oncologist, and the diagnostic radiologist in the rural or feeder hospital. On the downside, these teleradiology techniques are working so well that many local radiologists are now complaining of competition from the larger, better-known radiology centers. Rural, small community, and suburban

clinics are finding it easier to send images electronically to the remote center than to carry films to the local hospital for interpretation.¹³ In fact, it is now not uncommon for some hospitals to outsource radiology readings to qualified radiologists in India or other countries.

Patient Medical Records and Medical Data Banks

Telemedicine networks allow the transfer of patient medical information from clinic to clinic and inpatient facility to inpatient facility. With open access to all health providers involved in a patient's care, such systems cut down on duplicative and contradicting therapies and help eliminate adverse drug reactions. Medical data banks¹⁴ available at the provider's fingertips encourage the use of such data banks and their recommended treatment plans or guidelines. The existence of such programs with the patient's complete medical history makes research into outcomes and total care experiences possible across a wide variety of system facilities.

Videoconsultation and Remote Presence Technology

This is the area of telemedicine that has taken the lion's share of the attention directed to the subject. Magenau¹⁵ indicates that despite the progress in this field in the United States, Europe, which is free of many of our barriers, is far ahead. With the videoconsultation and modern telemedicine techniques it is possible to have a consultation between a treating physician, the patient, and the telemedicine consultant in which the telemedicine physician meets the patient, views the patient, reviews the medical records, pathology, laboratory, medical imaging, listens to the patient's heart and lungs, and can even palpate the patient via virtual reality gloves.¹⁶ Dermatology consults in particular have thrived in the videoconsultation environment.

Videoconsultation techniques are a godsend in remote or rural medical situations. They can be adopted to help with emergency service care and ambulance transfer to the hospital. Prisons and jails can use the techniques to avoid transferring prisoners to extramural medical facilities. The military can use the techniques in treating frontline casualties. In fact, the military is one of the largest current users of videoconsultations and has satellite connections to over 70 remote sites. The military is now experimenting with remote-controlled battle front surgery using three-dimensional virtual reality screens and robot or surrogate surgeons. Today, videoconsultation techniques are widely used in states such as Alaska and Hawaii, where remote areas are common.

Perhaps one of the most fascinating evolutions of telemedicine and videoconsultation is the refinement of remote presence technology. Created by California-based InTouch Health, a 5-foot-tall robot displays a real-time video of the physician on its flat-screen "head." On top of his head sits a camera that serves as eyes, which capture images of the patient that are simultaneously transmitted to the physician.

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The physician sits at a base station from home or other remote location, and he or she uses a joystick to control the head movements and travel of the robot throughout the hospital. Not only is the physician able to view laboratory results, monitor readings, and x-rays from their base station, but the doctor is also able to visualize and interact with patients in real time. Interestingly, a recent study by Kavoussi and other researchers at Johns Hopkins discovered that patients were just as happy with a “telerounding” physician as they were with seeing the physician in person.¹⁷ Indeed, physicians are able to rely upon this technology to maximize their contact with their patients.

Telepathology, Telecolposcopy, and Physician Reluctance

The same digital imaging and image enhancement techniques used above can be used for microscopic views, the basis of both histology and colposcopic exams. For several reasons, the techniques, although useful, have not become as popular as teleradiology. Pathologists cite the lack of the gross specimen, the ability to make their own representative “cuts,” and loss of depth perception as their principal objections. Colposcopists bring up their disappointment with cervigraphy, a previous imaging technique. It appears, however, that both techniques are effective and will bring an additional method of consultation to underserved areas, but telemedicine’s failure to win widespread use in these two procedures illustrates a major problem: physician reluctance to use telemedicine. The usual argument is that the only way to practice medicine is face to face and in person. This defeats one of the principal aims of telemedicine, which is to provide care where that face-to-face in person meeting is not possible. It is also very apparent that a large number of physicians are reluctant to use what they see as new technology. It is easy to write this off to cultural lag, but critics of the profession promote this as further evidence of a profession striving to hold onto the status quo and adopting technologies long after the technology is obsolete. This reluctance to accept telemedicine is likened to the professions’ previous failures in the field of health informatics.

Along with the reluctance of some physicians to use telemedicine, other barriers prevent its rapid implementation in the United States. The first is the lack of the communications infrastructure in the American hinterlands to permit rapid, inexpensive, undistorted transmission of medical data. The second is the presence of state licensing requirements, and the third is a series of other legal concerns. In the United States, telemedical practice has flourished in locales such as Hawaii or Alaska where geography presents unique challenges to conventional health care delivery.

Rural Telecommunications Infrastructure and Site Equipment

A fully developed and sophisticated communications infrastructure is necessary to transport telemedicine information between rural patients and central specialists. This infrastructure is absent in many of the areas most in need

of telemedicine. At the present time, there is no clear-cut method of funding the development of the needed infrastructure. Furthermore, the general economic recession of 2002 has had a tremendous impact upon telecom companies in the United States. If the local carrier does the infrastructure buildout, local access and transport areas rate schedules make the cost of telemedicine prohibitive or, at best, too expensive to be practical. The Telecommunications Act of 1996¹⁸ attempts to secure universal service¹⁹ in regard to health, education, and safety for everyone in the United States regardless of location. The act aims to place telemedicine services at the disposal of rural residents at the same rates as those paid by urban residents. The act instructed the FCC to set up a Joint Working Group on Telemedicine, and Section 709 calls on the Joint Working Group to cooperate with the Department of Health and Human Services in a report to Congress. The FCC went one step further and set up a Telecommunications and Health Care Advisory Committee. It behooves anyone truly interested in telemedicine to read the act carefully and to secure the reports of the working group and the committee created by the FCC.

Although sophisticated equipment is needed at each remote site and providers have worried about potential liability for equipment failure, these problems do not appear to be the barrier some expected them to be. First, the cost of site equipment has dropped more rapidly than anyone could have predicted even 3 to 4 years ago and the one-time outlay today is often comparable to one month’s transmission costs in a busy clinic. Second, the general rule for health care providers is that the provider is liable for injuries resulting from negligence in the care, maintenance, or use of the equipment but the manufacturer and seller are liable for injuries resulting from latent defects in the equipment. There seems little reason to believe this general rule will not apply to telemedicine equipment as well.

LEGAL ISSUES

FDA Regulation as a Medical Device

The FDA was given the authority to regulate medical devices in 1976 under the Medical Device Amendments of 1976.²⁰ The Safe Medical Device Act of 1990²¹ built upon the 1976 foundation and created an extensive FDA regulatory scheme to ensure the safety of medical devices. The scheme is a cumbersome one requiring registration, premarketing notification, inspection of the manufacturing facility, warnings to purchasers, and reporting of adverse events for all devices and premarket approval of all new devices. Premarket approval is a lengthy process requiring proof of the safety and efficacy of the device. Section 321(h) of the Food, Drug, and Cosmetics Act defines a medical device very broadly.²² It would appear that both the telemedicine systems and their components fall under the definition of a medical device as established by Section 321(h). It also appears that the FDA will assume a regulatory role in telemedicine.

The FDA has shown great interest in teleradiology and is already regulating the hardware of teleradiology systems

and the software connected with medical imaging systems.²³ To date, FDA regulation appears to be dependent upon whether the device is promoted as a medical device or not. Equipment marketed for general communication purposes has escaped FDA attention. In fact, the FDA's approach has been thoughtful and helpful. However, if the FDA acts as most administrative regulatory agencies are so inclined, it will gradually extend its authority over all aspects of telemedicine. If the FDA attempts to regulate telemedicine systems as a whole, it could be a disastrous turn of events for the development and use of telemedicine. The Byzantine nature of the FDA approval system could wreak havoc on upgrading systems, as well as discouraging manufacturers of communications hardware and software from entering the telemedicine field. One can envision the rapidly evolving telemedicine technology suddenly brought to the glacial pace that only an administrative agency may invoke. We should watch this area of regulation closely.

Licensing and Credentialing

State licensing laws are highly individual and set up a barrier to the practice of telemedicine across state lines. Each state has the right to license physicians to practice medicine as part of the state's police power to protect the health of its citizens. This police power is granted the states by the Constitution²⁴ and two Supreme Court decisions.²⁵ Therefore, there is a presumption that the state will find anyone examining, diagnosing, or treating a state resident practicing medicine within that state. The Federation of State Medical Boards (FSMB) has maintained the necessity of individual state licensure in its Model Act to Regulate the Practice of Medicine by Other Means Across State Lines.²⁶

At the time of this writing in 2005, there are 45 states in the United States that either statutorily require full medical licensure in the state where a physician is practicing telemedicine or require licensure by default because there is no mention of a special purpose or telemedicine license.²⁷ In 2005, there are 13 states that are statutorily silent on the issue of medical licensure requirements for telemedical practice.²⁸ At present, there are numerous telemedicine-related bills being considered in several state legislatures. Only time will tell when all states have finally codified some form of telemedicine law. In addition, there are 5 states that require a special purpose license.²⁹ For example, Texas law provides that a person shall be considered to be "practicing medicine" if the person is physically located in another jurisdiction and through any medium performs an act that is part of patient care service initiated in Texas that would "affect the diagnosis or treatment of a patient."³⁰ The "special purpose license" is required for a physician who is actively licensed in another state and certified in a medical specialty.³⁰ The law also requires that an applicant for a special purpose license pass the Texas Medical Jurisprudence examination, and practice is limited to the medical specialty upon which the license is granted.³⁰ A special purpose license is not required for a limited number of "episodic consultations" to a Texas physician who practices in the same medical specialty, consultation services provided to a

Texas medical school, or for medical assistance if no charge is made.³⁰

The FSMB Model Act would permit a duly licensed practitioner in one state to obtain a limited license in another state solely for the purpose of practicing medicine across the state line. The FSMB Model Act has been criticized in telemedicine circles because it permits the adoption of somewhat different standards by each of the states. California has eliminated licensure requirements for the consultant who "shall not open an office, appoint a place to meet patients, receive calls from patients within the limits of this state, give orders, or have ultimate authority over the care or primary diagnosis of a patient who is located in this state"³¹—a limited relief at best. Several other states have introduced licensing requirements applicable to telemedicine or had preexisting statutes that might be applied to telemedicine.³² However, none of the states appear to have adopted the FSMB Model Act in its entirety. At this time it would appear that four rather shaky conclusions can be drawn concerning interstate licensure (Box 40-3).

Credentialing

Little attention has been directed to the credentialing of telemedicine specialist physicians either by their specialty organizations³³ or by the organizations (hospitals and/or MCOs) of the treating physician and, to date, it appears that existing consultation criteria control. The Joint Commission for the Accreditation of Healthcare Organizations has delineated no credentialing criteria specifically for telemedicine consultants. Several bills have been introduced within state legislatures pertaining to telemedicine consultants and practice within state-regulated hospitals, but the content and progress of those bills is currently not available to the authors.

Confidentiality

Fears that the confidentiality of patient medical information would be violated has also acted to slow the spread of telemedicine. While true confidentiality of medical information is probably a myth in this age of multiple providers, third-party payors, and fourth-party auditors, it has been one of the legal issues most commonly raised in discussions of telemedicine. Moreover, the protection of the integrity

Box 40-3

State law still controls licensure and no federal preemption is likely to occur in the near future. Irregular, infrequent physician to physician consults will not require a license in most states. Regular, frequent consults, direct patient contacts, and patient interventions will require either a limited or full license. The state licensure statutes vary to such a degree that the relevant statutes should be carefully reviewed before accepting any of the generalities listed above.

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of the medical information is commonly lumped with confidentiality as a single issue. Indeed the fear of “hackers,” who are capable of not only observing teleconsultations and medical records but of altering the records as well, seems to be the primary concern of many commentators.³⁴ The fact that a readily accessible paper record is subject to the same sort of scrutiny, alteration, or destruction by a much less sophisticated trespasser seems to have been forgotten in the wake of widespread reports of hacker prowess. As the National Research Council notes, attention must center on methods of protecting the confidentiality and integrity of sensitive electronic health care data rather than opposing its use in health care.³⁵

To think that electronically transferred information cannot be protected or to forbid information transfer done for the benefit of the patient because it may violate some state confidentiality regulation makes no sense. Electronic patient data is transferred across state lines daily just as information in all fields of modern endeavor is. Today, information knows no state boundaries. The benefit to the patient and to society as a whole of permitting the electronic transfer of health data makes state confidentiality regulations obsolete. The 1986 Electronic Privacy Act³⁶ prohibits the interception of any electronic communication but offers no practical protection criteria.

Telemedicine needs practical guidelines as to what steps it must take to protect personal medical information from unauthorized persons or institutions. Congress has addressed that issue in the Health Insurance Portability and Accountability Act (HIPAA) of 1996.³⁷ The final HIPAA directive on the subject, entitled *Standards for Privacy of Individually Identifiable Health Information*, was published in late 2002.³⁸

Malpractice Insurance

The telemedicine consultant must carefully determine whether he or she is covered by malpractice insurance.³⁹ Some malpractice insurance carriers specifically exclude coverage for telemedicine. These exclusion clauses are usually based largely on the licensure issue, although there is no doubt that the physician–patient relationship and conflict of laws issues discussed below enter into the carrier’s decisions.

Malpractice Issues

Fortunately, there have been few malpractice cases involving telemedicine. Unfortunately, those malpractice cases that have arisen have reached settlement and we are unaware of any that have reached the appeals level. Dalton reports the same lack of precedents in the European Union.⁴⁰ Therefore, there are no binding precedents in telemedicine law. Despite this lack of precedents, physicians continue to worry and lawyers continue to speculate about the potential of malpractice actions for telemedicine activities. The foremost of the issues is whether a telemedicine physician assumes a duty of care for the remote patient. In other words: does a physician–patient relationship exist?

Physician–Patient Relationship

Classically, the physician who discusses a patient with the treating physician does not establish a physician–patient relationship with the patient.⁴¹ There is nothing inherent in the electronic aspect of such discussions that should change that concept. However, when telemedicine is used for remote diagnosis, interactive videoconsultations, and remote physicians take a more active role in the treatment of the patient, perhaps even including surgery, the physician–patient relationship may well be established. Someday, the definition of a patient–physician relationship may also reflect the changed health care delivery systems possible with telemedicine.⁴²

There are a long line of telephone cases, certainly an early form of telemedicine, that establish that a physician–patient relationship exists when a physician attempts to diagnose, advise, or treat a patient via the phone.⁴³ There are also a long line of cases that establish a physician–patient relationship for physicians such as pathologists, radiologists, and electrocardiologists who are active in the care of the patient but that never have a face-to-face meeting with the patient.⁴⁴ The reasoning in these case lines would appear to be directly applicable to comparable telemedicine cases and indicate that a physician–patient relationship will exist in many telemedicine situations. The physician–patient relationship appears particularly clear in situations where the telemedicine physician meets with both the treating physician and the patient via the videoteleconference and takes part in developing the history and physical examination of the patient through the use of various media and then participates in developing a treatment plan.

Jurisdiction

It is a principle of conflicts of law that in a personal injury case the situs of the injury determines the jurisdiction unless some other state has a more significant relationship. These dual factors make it likely that the patient would have no difficulty instituting suit in his or her state of residence and may be able to bring suit in the telemedicine physician’s state if the forum was more appealing. Diversity of residence and the value of the case may also add the possibility of the federal court system as an applicable forum. The possibility of the plaintiff being able to bring suit in any state the telemedicine physician has electronic ties to, and thus have an almost unlimited opportunity to forum shop, although widely speculated on in the medical literature, does not appear to be a serious concern at this time.

More complicated conflict of laws situations may exist in malpractice cases where the patient is a resident of a country other than the United States and has no local provision for malpractice litigation, or in patients treated in space. A wide variety of cases will have to reach the appellate level before all these jurisdictional issues become clear-cut.

Abandonment

While most legal commentators think it is highly unlikely that a telemedicine physician would be held to have

QUERY: Please provide box title.

Box 40-4

The patient and treating physician know of the need for any continuing treatment.
All parties know and agree on who will provide that care.
The patient knows who to call in an emergency.
The treating physician knows how and when to contact the telemedicine physician.

abandoned a patient still under the care of the treating or referring physician, the telemedicine physician must be sure to document the items listed in Box 40-4.

Reimbursement

Most physicians have a difficult time securing reimbursement for telemedicine services. At this time, there is no consistent national policy on reimbursement for telemedicine services. Most telemedicine is currently supported by demonstration grants from federal, state, or private sources. In general, insurers have refused to pay for telemedicine services. Medicare will pay for teleradiology providing the films are transmitted and read according to the standards established by the American College of Radiology. On July 1, 2001, the Health Care Financing Administration (HCFA) was renamed the Centers for Medicare and Medicaid Services (CMS). CMS will allow Medicare to pay for telemedicine in designated health care shortage areas, and will allow Medicaid areas to establish their own telemedicine policies. CMS has been directed to establish national standards for telemedicine reimbursement and has set up several test areas to test plans. Once Medicare and Medicaid have such a standard, it is likely that private insurers will adopt a similar payment scheme.⁴⁵

CONCLUSION

Telemedicine has demonstrated its potential to offer widespread access to sophisticated medical care, curtailed health care delivery costs, and homogeneous health and health-related education opportunities. However, progress in telemedicine has revealed a variety of potential barriers to its widespread application even when the technical infrastructure is well established. These barriers include technical limitations, reimbursement issues, equipment and networking costs, and appropriate scientific studies to document efficacy and cost-effectiveness. These issues may prove to be only transient disincentives that can be surmounted.

A number of medical and legal issues exist that may not be as readily resolved by traditional methods of legal analysis. Some examples include: (1) the potential need to redefine the nature of the physician-patient relationship; (2) the protection of patient privacy and confidentiality; (3) the balance between federalism and states' rights in determining the medical licensure status of physicians who practice telemedicine; and, (4) the political and regulatory obstacles that are sure to require solutions based on

national consensus. The practice of telemedicine will change the interactions and relationships between physician/patient, physician/physician, and physician/third-party payor.

One thing is certain: telemedicine enhances man's ability to deliver medical care. Perhaps the real question is: What price is mankind willing to pay to provide health care without boundaries? At this point, all we know is that the answer lies somewhere between here and cyberspace.

Endnotes

1. See U.S. Federal Food and Drug Administration, Center for Devices and Radiological Health, *White Paper on Telemedicine Related Activities* (1996); see also Joint Working Group on Telemedicine, *Executive Summary: Telemedicine Report to Congress* (Jan. 1997), <http://www.ntia.doc.gov/reports/telemed>.
2. See California Telemedicine Development Act of 1996, 1996 Cal. Stat. 864 §1(d).
3. Dalton mentions intercontinental programs in pathology, obstetrics, radiology, cardiology, oncology, dermatology, surgery, laparoscopy, and endoscopy. K. J. Dalton, *Legal Aspects of Telemedicine Across State Borders*, LL.M. Dissertation, Cambridge University (Aug. 28, 1998); M.R. Campbell, *Surgical Care in Space*, 70 *Aviation, Space and Environmental Medicine* 181 (1999).
4. 45 C.F.R. Part 164.
5. See 67 Federal Register (Aug. 14, 2002) Final Rule, Standards for Privacy of Individually Identifiable Health Information. See also Proposed Rules, 67 Federal Register 14776 (2002) (to be codified at 45 C.F.R. Parts 160 and 164).
6. Department of Health and Human Services, Office of Civil Rights, Office of the Secretary, 45 C.F.R. Parts 160 and 164, Rin: 0991-AB14, Standards for Privacy of Individually Identifiable Health Information. Action: Final Rule.
7. Young, *FTC-Lilly Settlement Sheds Light on E-Mail Privacy with Patients*, 59 *American Journal of Health System Pharmacy* 509 (2002); Current Developments, *Eli Lilly Settles FTC Charges Concerning Disclosure of E-Mail Addresses of Prozac Users*, 19 *The Computer & Internet Lawyer* 27 (2002).
8. See Kolker, *This File Will Not Destruct*, 24 *American Lawyer* 11 (2002).
9. Mandl et al., *Social Equity and Access to the World Wide Web and E-Mail: Implications for the Design and Implementation of Medical Applications*, Proceedings of AMIA Symposium 215 (1998).
10. Kane & Sands, *Guidelines for the Clinical Use of Electronic Mail with Patients*, 5(1) *Journal of the American Informatics Association* 104 (1998).
11. See Heusner, *The E-Mail Connection*, 82 *Minnesota Medicine* 22 (1999); Jurevic, *When Technology and Health Care Collide: Issues with Electronic Medical Records and Electronic Mail*, 66 *U.M.K.C. Law Review* 809 (1998); see also, Bernstein, *Why and How to Use Technology*, 33(1) *Trial* 93 (1997); Spielberg, *Online Without a Net*, 25 *American Journal of Law and Medicine* 267 (1999); Subscriber's Manual, www.medem.com (2002).
12. See 45 C.F.R. §164.506.
13. See D.F. Meek, *Telemedicine: How an Apple (or Another Computer) May Bring Your Doctor Closer*, 29 *Cumberland L. Rev.* 173, 175 (1998).
14. Examples of such data banks include the highly successful Helix data bank for clinical geneticists and several regional data banks dealing with diabetes and diabetic complications. See P. Tarczy-Hornoch et al., *Creation and Maintenance of Helix, a Web Based Database of Medical Genetics Laboratories*, 1998 Proceedings of AMIA, 341; T.H. Williamson & D. Keating, *Telemedicine and Computers in Diabetic Retinopathy Screening*, 82 *British Journal of Ophthalmology* 5 (1997); P.C. Jones et al., *Nationwide Telecare for Diabetics*, 1998 Proceedings AMIA, 346.

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15. Jeff L. Magenau, *Digital Diagnosis: Liability Concerns and State Licensing Issues Are Inhibiting the Progress of Telemedicine, Communications and the Law* 25 (Dec. 1997).
16. Several examples of virtual gloves are currently undergoing clinical evaluation.
17. Ellison et al., 199 J. Am. Coll. Surg. 523–530 (2004).
18. Pub. L. No. 104-104 (codified in scattered sections of 47 U.S.C.).
19. *Id.* §§253 and 254.
20. 21 U.S.C. §§360c–360k.
21. Pub. L. No. 101-629, 104 Stat. 4511 (1990).
22. 21 U.S.C. §321(h) defines a medical device as: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component part or accessory, which is
 - (1) recognized in the official National Formulary, or in the United States Pharmacopeia, or any supplement to them,
 - (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man or other animals, or
 - (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purpose through chemical action within or on the body of man or other animals and
 - (4) which is not dependent upon being metabolized for the achievement of its primary intended purpose.

Only one of the three elements must be met to classify the object as a medical device.
23. See FDA, Center for Devices and Radiological Health, *Guidance for the Content and Review of 501(K) Notifications for Picture Archiving and Communications Systems and Related Devices* (1997).
24. U.S. Const. Amend. X.
25. *Dent v. West Virginia*, 129 U.S. 114 (1889); *Hawker v. New York*, 170 U.S. 189 (1898).
26. See Appendix 40-1 below.
27. Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.
28. District of Columbia, Florida, Maine, Massachusetts, Michigan, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, South Carolina, South Dakota, and Wyoming.
29. Alabama, Montana, Ohio, Oregon, and Texas.
30. See 22 TX ADC §174.2 and TX OCC §151.056.
31. Senate Bill 1665 §3, 1996–97 Reg. Ses. (Cal. 1996) (Enacted), codified in various sections of the Business and Professions Code, Health and Safety Code, Insurance Code, and Welfare and Institutions Code.
32. Maryland's statute, while not specific to telemedicine, provides much the same protections as does California's statute (Md. Ann. Code §14-302); Colorado (Col. Rev. Stat. §12-36-106(b), Delaware (Del. Code Ann. §1726), Indiana (Ind. Code Ann. §25-22.5-1-2 (4)) Missouri (Mo. Ann. Stat. §334.010), Vermont (Vt. Stat. Ann. §26-23-1313), and Nevada (Nev. Rev. Stat. §630.047) allow consultations across state lines; Alabama, while specifically stating that telemedicine is the practice of medicine (Ala. Code §34-24-501(2)), also allows practice across state lines if it occurs less than 10 times per calendar year (Ala. Code §34-24-505(b)); Oklahoma's Telemedicine Act (Okla. Stat. Ann. §6801), while covering reimbursement and informed consent, does not deal with licensing directly; Mississippi's statute on telemedicine (Miss. Code Ann. §73-25-34) specifically requires a state license for the practice of telemedicine across state lines (although the Mississippi Attorney General has rendered an opinion that radiologists interpreting films sent outside the state are not practicing medicine in Mississippi); Texas (Tex. Rev. Stat. Ann. Art. 4495(b) §3.06(I)), South Dakota (S.D. Codified Laws §36-4-41), and Florida (Fla. Stat. Ann. §458.3255) have provisions that closely resemble Mississippi's; Minnesota (Minn. Stat. Ann. §147.081) and Oregon (Or. Rev. Stat. §677.085) define the practice of medicine in a way that indicates a license is required for telemedicine; Kansas and Ohio have licensing provisos that may permit a telemedicine practitioner to receive a limited license to practice.
33. The American College of Radiology is the notable exception to this generality.
34. See L. Gostin, *Health Information Privacy*, 80 Cornell L. Rev. 451 (1995); see also Gilligan & Imwinkelried, *Cyberspace: The Newest Challenge for Traditional Legal Doctrine*, 24 Rutgers Computer and Technology Law Journal 305, 307 (1998).
35. *Technology is Changing the Health Data Security Landscape*, Health Data Mgmt. (Sept. 1997), quoted and cited in C.J. Young, *Telemedicine: Patient Privacy Rights of Electronic Medical Records*, 66 U.M.K.C. Law Rev. 921, 928 (1998).
36. 18 U.S.C. §§2510 *et seq.*
37. Pub. Law 104-191, 1996 (codified in scattered sections of 42 U.S.C.). See specifically DHHS Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. §§160–164, 10-1-01. See also discussion of HIPA in Chapter 16 (this volume).
38. DHHS Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. §§160–164, 10-1-01, Final rule, Federal Register, Aug. 14, 2002, 67(157):53182–53273, to be codified at 45 C.F.R. Parts 160–164.
39. See Meek, *supra* note 13, at 183; see also Dalton, *supra* note 3, at 52.
40. Dalton, *supra* note 3.
41. See *Discussion with Consultants*, 5(2) Legal Medicine Perspectives 10 (1998); *Lopez v. Aziz*, 852 S.W. 2d 303 (1993).
42. See R.C. King and S.M. Rodman, *The Past, Present, and Future of Medicine and Otolaryngology on the Internet*, in E.N. Myers, S.D. Bluestone, D.E. Brackman, et al. (eds.), *Advances in Otolaryngology-Head and Neck Surgery*, Vol. 15, 245–263 (Mosby, Inc., St. Louis, Mo., 2001).
43. *Hamil v. Bashline*, 305 A. 2d 57 (1973); *O'Neil v. Montefiore Hospital*, 202 N.Y.S. 2d 436 (1960); *Wheeler v. Yettie Kersting Memorial Hospital*, 866 S.W. 2d 32 (1993).
44. *Rule v. Cheeseman*, 317 P. 2d 472 (1957); *Dougherty v. Gifford*, 826 S.W. 2d 668 (1992); *Waters v. Rinker*, 520 N.E. 2d 468 (1988); *Dodd-Anderson v. Stevens*, 905 F. Supp. 937 (1995).
45. See also Oklahoma Telemedicine Act, *supra* note 32.

APPENDIX 40-1: A MODEL TELEMEDICINE ACT

Proposed by the Federation of State Medical Boards of the United States Inc. in April 1996. An Act to Regulate the Practice of Medicine across State Lines

Legislative Findings and Purpose

The legislature hereby finds and declares that, due to technological advances and changing practice patterns, the practice of medicine is occurring with increasing frequency across state lines and that certain technological advances in the practice of medicine are in the public interest. The legislature further finds and declares that the practice of medicine is a privilege and that the licensure by this State of practitioners outside this State engaging in such medical practice within this State and the ability to discipline such practitioners is necessary for the protection of the citizens of this State and for the public interest, health, welfare, and safety.

Definition

The practice of medicine across state lines means:

1. the rendering of a written or otherwise documented medical opinion concerning diagnosis or treatment of a patient within this State by a physician located outside this State as a result of transmission of individual patient data by electronic or other means from within this State to such physician or his or her agent; or
2. the rendering of treatment to a patient within this State by a physician located outside this State as a result of transmission of individual patient data by electronic or other means from within this State to such physician or his or her agent.

License Requirement

No person shall engage in the practice of medicine across state lines in this State, shall hold himself or herself out as qualified to do the same, or use any title, word or abbreviation to indicate to or induce others to believe that he or she is licensed to practice medicine across state lines in this State unless he or she is actually so licensed in accordance with the provisions of this article.

Issuance of License

The Board shall issue a special purpose license to practice medicine across state lines upon application for the same from a person holding a full and unrestricted license to practice medicine in any and all states of the United States or its territories in which such individual is licensed, provided there has not been previous disciplinary or other action against the applicant by any state or jurisdiction. In the event of previous disciplinary or other action against the applicant, the Board may, in its discretion, issue a license to practice medicine across state lines if it finds that the previous disciplinary or other action does not indicate

that the physician is a potential threat to the public. An individual shall submit an application to the Board on a form provided by the Board and shall remit to the Board a reasonable fee for such license, the amount of the fee to be set by the Board. A license to practice medicine across state lines issued by the Board limits licensee safely to the practice of medicine across state lines as defined herein. The special purpose license in this State is valid for the term of —years (*to be set by the Board to conform with renewal requirements for full and unrestricted licenses*) and is renewable upon receipt of a reasonable fee, as set by the Board, and submission of a renewal application on forms provided by the Board.

Effect of License

The issuance by the Board of a special purpose license to practice medicine across state lines subjects the licensee to the jurisdiction of the Board in all manners set forth in the Medical Practice Act and implementing rules and regulations, including all matters related to discipline. In addition, the licensee agrees by acceptance of such license to produce patient medical records and/or materials as requested by the Board and/or appear before the Board or any of its committees within (*to be set by the Board*) days following receipt of a written notice issued by the Board. Such notice will be issued by the Board pursuant to any complaints or reports filed or any complaint initiated by the Board or any of its committees when records and/or materials are deemed relevant to said complaint or report. Failure of the licensee to appear and/or to produce records or materials as requested, after appropriate notice, allows the Board to suspend or revoke the licensee's special purpose license at its discretion. Notwithstanding any provision of state law to the contrary, such suspension or revocation of such license may be effected prior to a hearing, after appropriate notice and if the Board finds an ongoing and continuous threat to the public. Such action taken by the Board shall be deemed a disciplinary action, for purpose of action by any other state.

Patient Medical Records

Any licensee licensed under the provision of this Act shall comply with all laws, rules and regulations governing the maintenance of patient medical records, including patient confidentiality requirements, regardless of the state where the medical records of any patient within this State are maintained.

Exemptions

A physician who engages in the practice of medicine across state lines in an emergency, as defined by the Board, is not subject to the provisions of this Act. A physician who engages in the practice of medicine across state lines on an irregular or infrequent basis is not subject to the provisions

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of this Act. The irregular or infrequent practice of medicine across state lines is deemed to occur if such practice occurs less than once a month or involves less than ten patients on an annual basis, or comprises less than one percent (1%) of the physician's diagnostic or therapeutic practice. A physician who engages in informal practice of medicine across state lines, without compensation or expectation of compensation, is not subject to the provisions of this Act. (The practice of medicine across state lines conducted within the parameters of a contractual relationship shall not be considered informal and shall be subject to regulation by the Board.)

Sanctions

Any person who violates the provisions of this Act is subject to criminal prosecution for the unlicensed practice of medicine, and/or injunctive or other action authorized in this State to prohibit or penalize continued practice without a license. Nothing in this Act shall be interpreted to limit or restrict the Board's authority to discipline any physician licensed to practice in this State who violates the Medical Practice Act while engaging in the practice of medicine within this or any other State.

Adopted April 1996.