

# 2001 Telemedicine



## Report to Congress



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U.S. Department of Health and Human Services • Health Resources and Services Administration • Office for the Advancement of Telehealth



## Report to Congress

January 2001





THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

MAR 12 2001

The Honorable Richard B. Cheney  
President of the Senate  
Washington, DC 20510

Dear Mr. President:

With pleasure, I present the 2001 Report to Congress on Telemedicine. Embarking on a new century and millennium, it is fitting to provide you with an overview of an industry that uses advanced computer and communications technologies to help disadvantaged Americans gain greater access to needed health care services.

In American frontier communities, such as those found in the Dakotas, Idaho, Montana, Oregon, Washington or Wyoming, patients often travel hundreds of miles or more to consult a primary care practitioner. Even in more populated rural areas they must travel long distances to access specialty care such as cardiology, dermatology or psychiatry. In rural Montana an ambulance may take an hour to arrive in an emergency and then an additional hour or more to reach a hospital. In remote places such as Alaska or the Pacific Basin thousands of miles must be traveled for specialty care. And geography is not the only factor in patient isolation. In urban areas, the elderly, chronically ill and disabled often face immense hurdles in accessing basic or specialty health care.

Telemedicine and telehealth have begun to bridge the gap between health care "haves" and "have nots." Public and private telemedicine networks now provide services in a wide range of settings from rural hospitals, clinics and schools, to urban prisons and homes. Tele-homecare provides oversight and assistance to elderly shut-ins, the disabled or rehabilitating patients.

Since the Department of Commerce's 1997 Report to Congress on Telemedicine, new trends have emerged, notably the growth and use of the Internet by consumers looking for health information, drug prescriptions and consultation. At century's end, the Health Care Financing Administration began reimbursing telemedicine consultations, while the Federal Communication Commission's Rural Health Care Program entered its second year of supporting telecommunications transmission costs for rural health care providers.

Despite these changes, many barriers to the proliferation of telemedicine remain. For example, more states have passed restrictive licensure laws, requiring state licensing for out-of-state telemedicine practitioners practicing electronically across state borders. The Internet, for all its great benefits, also raises concerns about patient privacy and safety.

Congress has played an important role in nurturing the development of the telehealth industry. I hope to continue to work with you to expand the reach of this critical service to the underserved in both rural and urban America. Thank you for your critical support of telemedicine and telehealth providers in the United States.

Sincerely,

Tommy G. Thompson

Enclosure

This letter was  
also sent to:

The Honorable  
James M. Jeffords  
Chairman, Committee on  
Health, Education, Labor  
and Pensions  
United States Senate

The Honorable  
Edward M. Kennedy  
United States Senate

The Honorable  
W.J. Tauzin  
Chairman of the  
Committee on Energy  
and Commerce  
House of Representatives

The Honorable  
John D. Dingell  
House of  
Representatives





THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

MAR 12 2001

The Honorable J. Dennis Hastert  
Speaker of the House of Representatives  
Washington, DC 20515

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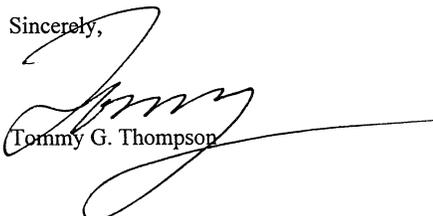
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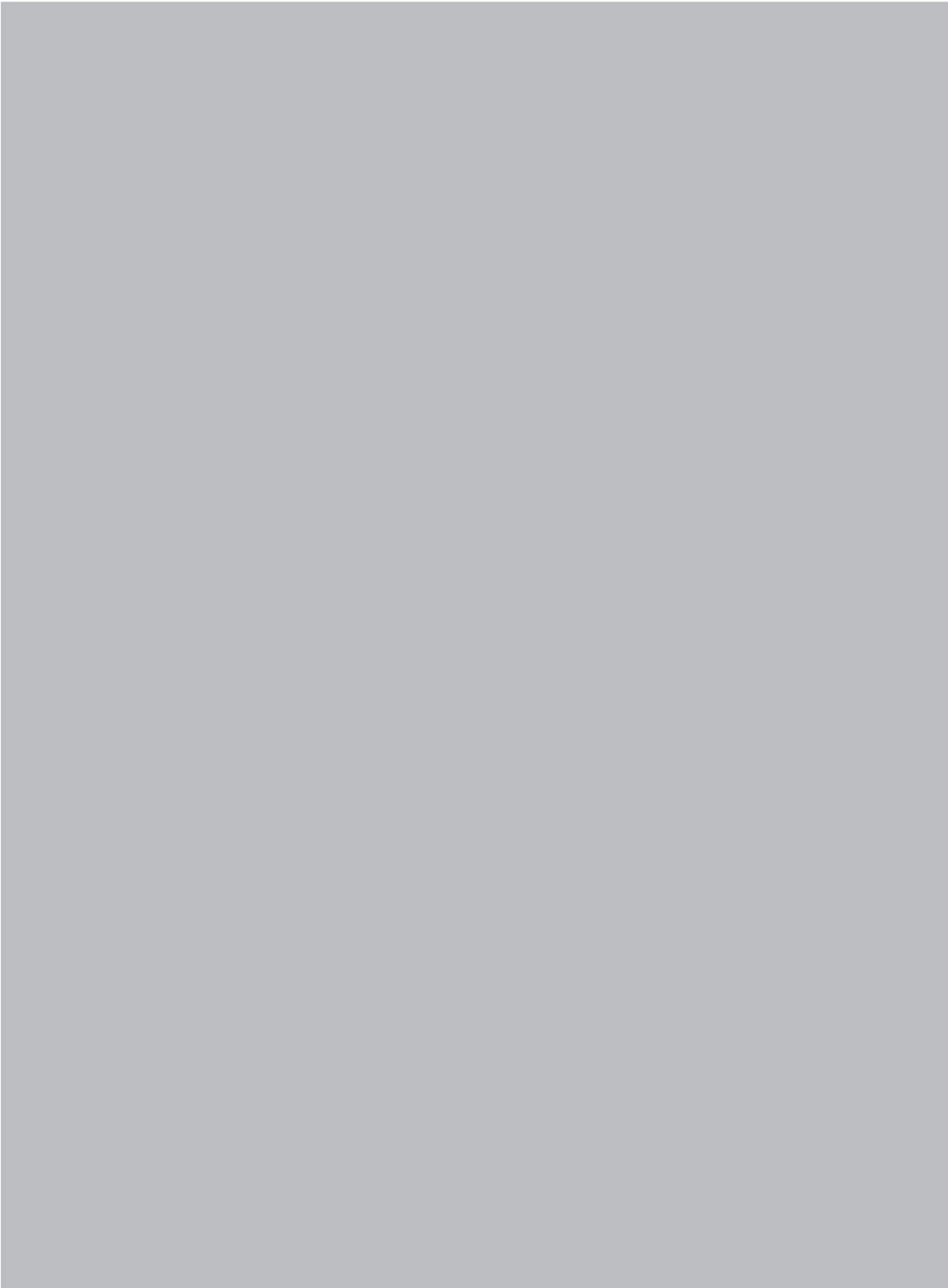
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# Executive Summary

The Healthcare Research and Quality Act of 1999, Section 6, requires the Secretary of Health and Human Services (DHHS) to submit a Report to Congress on Telemedicine by 2001. Congress requested that the Report describe barriers to telemedicine, determine the extent of patient and physician satisfaction with this mode of health delivery and assess patient benefits from telemedicine services.

What exactly is meant by telemedicine and telehealth? In the Department of Commerce's 1997 Report to Congress, "telemedicine" referred to "the use of electronic communication and information technologies to provide or support clinical care at a distance."<sup>1</sup> Telehealth is a broader concept. For the purposes of this Report, telehealth is defined as the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration.

## CURRENT TRENDS

One of the most important trends to emerge over the past four years is the remarkable growth and development of the Internet. While much of this report focuses on telehealth providers and the barriers they face in expanding the delivery of telehealth, this is only one part of the story. The Internet is dramatically changing the way consumers access health information, receive diagnostics and purchase pharmaceuticals. According to the Federal Trade Commission (FTC), consumer searching for online health information is increasing dramatically; it is predicted that 30 million Americans will seek health information online by 2001.<sup>2</sup>

The Internet will most likely play a key role in expanding the reach of telehealth and telemedicine to the average consumer. However, this potential also brings other concerns about state jurisdiction

and enforcement, physician and other health provider cross-state licensure, privacy and safety issues, as discussed throughout the Report to Congress.

## KEY ISSUES

Key issues affecting the telemedicine and telehealth industry have remained the same over the past five years but their relative importance has changed with the advent of dramatic technology changes such as the wide spread adoption of the Internet. These issues are:

- Lack of Reimbursement;
- Legal Issues;
- Safety and Standards;
- Privacy, Security and Confidentiality;
- Telecommunications Infrastructure.

*Lack of Reimbursement* remains a critical barrier to the expansion of telemedicine. Even though technology has made it easier to deliver health care services using advanced communications and computers, historically few public or private payers have covered them. The Balanced Budget Act of 1997 (BBA) expanded coverage options for telemedicine but also included several requirements that preclude telemedicine's use under conditions where it is commonly being used outside of Medicare. The BBA required the Health Care Financing Administration (HCFA), DHHS to pay for telemedicine consultation services as of January 1, 1999. Some current reimbursement eligibility requirements are outlined in Table 1.

In the first two years, many telemedicine practitioners found the requirements under the BBA mandate too narrow for most practical purposes. Between January 1, 1999 and September 30, 2000, HCFA had reimbursed 301

<sup>1</sup>1997, *Telemedicine Report to Congress*, U.S. Department of Commerce, P.1.

<sup>2</sup>Federal Trade Commission, *Protecting Consumers Online: A Federal Trade Commission Report on the First Five Years of Its Internet Law Enforcement Program*, December 1999.

## Table 1: **TELEMEDICINE REIMBURSEMENT REQUIREMENTS**

(Under the Medicare, Medicaid & SCHIP Benefits & Improvement Protection Act of 2000)

SCOPE	ELIGIBILITY REQUIREMENTS
GEOGRAPHIC SCOPE	Only patients located in Rural Health Professional Shortage Areas (HPSAs), counties in Non-MSAs and in approved Federal demonstration projects are eligible for telemedicine reimbursement. A list of HPSA shortage areas can be found at <a href="http://www.access.gpo.gov">http://www.access.gpo.gov</a> .
ELIGIBLE SERVICES/ CPT CODES	Eligible Current Procedural Terminology (CPT) codes include professional consultations, office visits, and office psychiatry services (codes 99241-99275; 99201-99215; 90804-90809; and 90862) and any additional services specified by the Secretary.
ELIGIBLE PRESENTING PRACTITIONER	The new law eliminates the requirement to have a telehealth presenter present a patient at a consultation unless it is medically necessary (as determined by the physician or practitioner at the distant site).
FEE-SHARING	The new law eliminates the fee sharing requirement between a consultant and referring physician.
ELIGIBLE TECHNOLOGY <sup>1</sup>	The new Act provides for reimbursement for store and forward technology in demonstration projects in Alaska and Hawaii but no other setting. HCFA's payment policy was developed to replicate a standard consultation as closely as possible. Under Medicare, a separate payment for a consultation requires a face to face examination of the patient. This requirement is consistent with the American Medical Association's description of a consultation. To that end, Medicare's teleconsultation rule requires a certain level of interaction between the patient and consulting practitioner because it offers the best substitute for a "face to face" consultation. Regardless of the technology, the patient must be present during the consultation.
HOME HEALTH CARE	The new Act clarifies that home health agencies "may adopt telehealth technology that it believes promotes efficiencies or improves quality of care, however, these technologies will not be specifically recognized or reimbursed under the home health benefit. Telehealth encounters do not meet the definition of a Medicare covered home health visit. But this does not preclude a home health agency from spending prospective payment dollars to furnish services outside of the Medicare home health benefit (i.e. for telehealth services to home health beneficiaries). If a physician intends that telehealth services be furnished while a patient is under a home health program of care, this should be recorded in addition to the Medicare covered home health services to be furnished."

<sup>3</sup> Medicare has historically reimbursed some telemedicine services that did not traditionally require face-to-face contact between a patient and practitioner. For example, Medicare covered EKG or EEG interpretation, teleradiology, and telepathology in most areas of the nation, in accordance with individual Medicare carrier policies.

claims for a total of \$20,000. Several factors may account for this small number. In particular, four requirements greatly limited the number of consultations eligible for reimbursement:

- Health Professional Shortage Area (HPSA) Requirement: Medicare paid for telemedicine services only in areas that lack adequate primary care services, even though many rural communities have little or no access to specialists, such as cardiologists or psychiatrists. Often the need for specialty services drives the demand for telemedicine services.
- Fee sharing requirement: HCFA mandated fee sharing, requiring specialists to provide services at a 75% fee that HFCA then reports as a 100% fee to the IRS. Other problems include accounting and fee tracking. Most rural practitioners are not equipped to track split fees. Finally, the eligible presenter must either be the referring physician or an employee of the referring physician. In many cases, the presenter is an employee of the local hospital or clinic.
- Eligible Presenters: Although registered nurses, licensed practical nurses and other similar types of health care professionals are the most common presenters in a telemedicine setting, they were not eligible for reimbursement.
- Eligible Current Procedural Terminology Codes: The allowable codes greatly restricted what services were reimbursable under the BBA and did not include

**BOX 1  
MEDICAID STATE  
COVERAGE**  
**Arkansas, California, Georgia, Iowa, Illinois, Indiana, Kansas, Kentucky, Louisiana, Montana, Nebraska, North Carolina, North Dakota, South Dakota, Oklahoma, Texas, Utah, Virginia, and West Virginia. In addition, Connecticut, Maine and Minnesota are piloting telemedicine programs.\***

those commonly used by telemedicine practitioners.

During its last two sessions, Congress introduced over nine bills that addressed some of these limitations. On December 20, 2000, Congress passed the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (“the Act”). Among other things, this Act eliminates the fee-split and telepresenter requirements and expands the types of presenters, current procedural terminology codes and geographic area limits that are eligible for reimbursement. (See Table 1) Appendix 1 presents a comparison of bills and a summary of the Act.

Historically, telemedicine reimbursement expansion has been prevented by a lack of data on which to judge changes in government expenditure. The Office for the Advancement of Telehealth (OAT) worked with the Center for Telemedicine Law (CTL) and OAT’s grantees to develop a series of cost models that show the impact of expanding telemedicine coverage on any third party payer’s expenditures. These “scoring” models have the advantage of being based on actual telemedicine experience in the field. Preliminary results suggest that many of the modest telemedicine reimbursement expansions introduced in the 106th Congress would have a minimal impact on Medicare expenditures. (For example, CTL/OAT estimates of the budgetary impact of Senate Bill 2505 range from \$50 to \$100 million over five years, as compared to the estimate of over a billion dollars for Telemedicine legislation in earlier years.)

Aside from Medicare reimbursement, 20 state Medicaid programs now reimburse for telemedicine

\* Sources: CTL “Medicaid Telemedicine and Telehealth Update”, July 2000, Health Care Finance Administration, DHHS

services and three other states are conducting pilot programs to assess telemedicine efficacy as shown in Box 1.

Some private insurers also provide limited telemedicine coverage in certain states. For example, California Blue Cross is currently funding the build-out of a statewide telemedicine network. Blue Cross - Blue Shield in Montana and North Dakota also provides some telemedicine coverage.

**Legal Issues**, particularly those relating to cross-state licensure, were thought to be among the most critical to the expansion of telemedicine five years ago. Today, traditional licensure issues remain important, but telemedicine practitioners have found that they can provide many in-state services. Moreover, consumer use of the Internet (which knows no borders) for health related information, purchase of prescription drugs and online consultations may create new legal and licensure issues, overshadowing the more traditional issues. For example, a consumer, located in state A, sues a health practitioner in state B, who has provided consultations to the consumer via a Web site. Who has jurisdiction in this case? How easily can state A enforce its state health licensure laws if the health practitioner is not licensed in state A?

Currently, about 26 states have laws regulating out-of-state telemedicine practitioners. Twenty-one require full licensure for an out-of state physician, providing telemedicine services to a patient located in that state. The other five states approach licensure in a variety of ways, such as California's registration requirement or Hawaii's permit for an out-of-state physician to provide consultation to an in-state licensed physician. A list of states' licensure laws is shown in Appendix 2.

While many more states restrict physicians'

interstate telemedicine practice, 12 states have adopted the Interstate Nurses Licensure Compact as shown in Box 2. The compact is a licensure model based on mutual recognition. Under it, the head of the nursing licensing board will administer the Compact for his/her state.

#### BOX 2

#### STATES THAT ADOPTED THE COMPACT

Arkansas, Delaware, Iowa, Maine, Maryland, Mississippi, Nebraska, North Carolina, South Dakota, Texas, Utah and Wisconsin

**Safety and Standards** have taken on greater importance in the past few years, not only in the world of telemedicine but also in the world at large. Without widely adopted standards and guidelines, interoperability and interconnection are not possible and the great potential of telemedicine will be difficult to achieve. Older equipment often will not interconnect with newer versions of the same machine. Different brands of the same equipment will not operate with one another, making networking across projects and sometimes within a project expensive and frustrating.

In addition to technical standards, there is a need for clinical protocols and guidelines. Examples of clinical protocols for telemedicine practice include preliminary scheduling procedures, actual consult procedures and telemedicine equipment operation procedures (such as telecommunications transmission specifications). The clinical technical standard for image quality in a video transmission would specify the technical standards needed by a specialist, such as a dermatologist, to achieve the high levels of image clarity and color required to correctly diagnose a patient. Only a few professional associations have adopted either clinical practice protocols or technical standards and guidelines, as shown in Table 2. Additionally, some government agencies have worked to develop technical guidelines for telemedicine interoperability.

Just as the wide adoption of telemedicine standards and protocols plays an important role in protecting public safety, the Food and Drug

Administration (FDA) and the Federal Trade Commission (FTC) play a critical regulatory role. The FDA ensures the safety and effectiveness of telemedicine medical devices and software, with the Center for Devices and Radiological Health (CDRH) as the lead agency. In oversight of telemammography, regulating standards, personnel, practice and procedures, the FDA plays an

even more critical role.

A number of federal and state regulatory agencies are working together to address health-related consumer problems on the Internet. They include state health authorities, FDA, the Justice Department and FTC. FTC plays a key oversight and enforcement role in Internet Commerce as illustrated in its December 1999 Report:

**Table 2: TELEMEDICINE STANDARDS AND GUIDELINES**

ORGANIZATION	STANDARDS AND GUIDELINES
AMERICAN TELEMEDICINE ASSOCIATION (ATA)	Telehomecare Clinical Guidelines: <a href="http://www.atmeda.org/news/guidelines.html">http://www.atmeda.org/news/guidelines.html</a> . ATA has also posted a May 1999 working draft of its Clinical Guidelines for Telepathology.
AMERICAN PSYCHOLOGICAL ASSOCIATION (APA)	Clinical Telepsychology guidelines posted on its Web site at <a href="http://www.apa.org/ethics/stmnt01.html">http://www.apa.org/ethics/stmnt01.html</a>
AMERICAN DERMATOLOGY ASSOCIATION	The American Dermatology Association has drafted proposals for clinical protocols for teledermatology.
AMERICAN NURSES ASSOCIATION	Clinical Core Principles on Telehealth, March 1998 Competencies on Telehealth Technologies in Nursing, March 1999
AMERICAN COLLEGE OF RADIOLOGY/NATIONAL ELECTRONIC MANUFACTURERS ASSOCIATION	Digital Imaging and Communication in Medicine (DICOM) Standards a uniform set of communication standards.
HEALTH LEVEL SEVEN	HL7 Standard for data exchange
KENNEDY KASSEBAUM HEALTH INSURANCE PORTABILITY ACT, 1996	Under the Administrative Simplification provision of HIPAA, the Act mandates the development and adoption of national electronic health transaction standards.
OFFICE FOR THE ADVANCEMENT OF TELEHEALTH	Practical technical guidelines based on OAT Grantee experiences at <a href="http://telehealth.hrsa.gov/">http://telehealth.hrsa.gov/</a> These guidelines are a work in progress. Currently include specifications for teledermatology, teleophthamology, emergency medical, telecardiology, telerehab. OAT has also funded a grant to develop a technical assessment center.

*Protecting Consumers Online: A Federal Trade Commission Report on the First Five Years of Its Internet Law Enforcement Program.* In this report the Commission discusses its activities to combat general consumer fraud and deception on the Internet. Since 1994, it has focused on the largest and “most egregious” fraud and deception examples, taking action against companies in more than 100 cases.

**Privacy, Security and Confidentiality** concerns are not unique to telemedicine. The U.S. Congress and individual state legislatures are all but certain to consider a wide range of privacy-related Internet legislation that could affect many industries next year. However, the unique privacy problems associated with personal patient information, such as HIV status, cancer or mental health, raise many important questions about personally identifiable information and its protection.

An important national privacy measure that may affect the telemedicine industry is the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under the Administrative Simplification provision of HIPAA, the Act mandates the development and adoption of a number of national electronic health transaction standards, including standards for electronic data exchange of health information; standards for the privacy of individually identifiable health information; a national provider identifier; an employer identifier and secure electronic signatures, among others.

According to the Act, the Secretary of HHS must develop final regulations relating to privacy standards by February 2000, if Congress has not acted by August 1999. In 1997, the Secretary together with the National Committee on Vital and Health Statistics (NCVHS), sent preliminary recommendations to Congress. In the absence of Congressional action by the mandated deadline,

HHS published a notice of proposed rulemaking in November 1999. Final HIPAA privacy rules were published December 28, 2000 and an HHS Fact sheet on these rules can be found in Appendix 7. The complete text can be found at: <http://aspe.hhs.gov/admsimp>.

The general principles, for the use and disclosure of personally identifiable health information, are applicable regardless of the form the information is kept in, the methods of transmission, the time sequence of its creation and use, or the way it is communicated.

HIPAA rules cover health plans (e.g., insurers, managed care organizations, federal health programs), clearinghouses (which unify data in standardized formats) and health care providers, who engage, directly or through contractual arrangements, in HIPAA standard electronic transactions.

Potentially the most challenging issue for telemedicine practitioners will be HHS’ proposal for federal privacy law to preempt state law only when states are less stringent. Thus, if state requirements are in conflict with federal ones, the rules providing more stringent privacy protections would prevail. Telemedicine practitioners could be faced with a patchwork of state privacy standards.

State laws governing health information exhibit wide discrepancies in protection, complexity and coverage as illustrated by a 50-state survey<sup>4</sup> of health privacy statutes that can be found at the Health Privacy Project Web site at: <http://www.healthprivacy.org/resources/statereports/exsum.html>.

OAT and the Assistant Secretary’s Office of Planning and Evaluation have recently funded a study and a conference entitled *Privacy, HIPAA*

<sup>4</sup>Health Privacy Project of the Institute for Health Care Research and Policy at Georgetown University.

and Telemedicine that will be completed in Spring 2001. The purpose of the study is to identify privacy issues unique to telemedicine and to determine how HIPAA privacy rules may affect telemedicine practitioners and patients.

Although a detailed discussion of consumer privacy and the Internet is beyond the scope of this Report, it is of growing concern to the public. To address this problem, industry has promoted self-regulatory mechanisms such as standards for Web sites. The Health on the Net Foundation (HON) (<http://www.hon.ch>) and TRUSTe (<http://www.TRUSTe.org>) have developed some of the most widely accepted standards and “privacy seals.” “Ethical principles” or “Ecodes” are another alternative. Two new industry coalitions called the Internet Healthcare Coalition ([ihealthcoalition.org/ethics/ecode.html](http://ihealthcoalition.org/ethics/ecode.html)) and the Health Internet Ethics Coalition have promoted this type of self-regulation.

Despite industry’s efforts to self regulate, agencies, such as the FTC, have found that industry self-regulation is not sufficient to protect consumer privacy on the Internet. In its report entitled, *Privacy Online: Fair Information Practices in the Electronic Marketplace, May 2000*, (<http://www.ftc.gov/os/2000/05/index.htm#22>) the FTC offers legislative recommendations to Congress that would set a basic level of privacy protection for all visitors to consumer-oriented commercial Web sites. The legislation would “require all consumer oriented commercial Web sites to the extent already covered by the Children’s Online Privacy Protection Act of 1998 (COPPA), to implement the four widely-accepted fair information practice principles.”<sup>5</sup> These principles are outlined below.

- **Notice:** Provide consumers clear and conspicuous notice of information practices;

- **Choice:** Offer consumers choices as to how their personal identifying information is used;
- **Access:** Offer consumers reasonable access to the information the Web site has collected about them;
- **Security:** Take reasonable steps to protect the security of the information collected from consumers.

#### **Telecommunications Infrastructure costs**

continue to represent a large percentage of overall costs in a telemedicine project’s monthly budget. To alleviate some of this burden, the Telecommunications Act of 1996 charged the FCC to administer the Universal Service program, which would provide rural health care providers with a discount on their telecommunication transmission charges equaling the difference between urban and rural transmission rates.

In 1997, the FCC established the Universal Service Administrative Company (USAC), a separate, not for profit entity, to oversee both the E-Rate discount for Schools and Libraries and the Rural Health Care Program (RHCD). USAC’s Rural Health Care Program issued its first funding commitments on June 25, 1999, five days before the end of the first 18-month program year. In total, 483 rural Health Care Providers received \$3.4 million out of a possible \$400 million, which equaled the total requested support for completed applications received by USAC that year (January 1, 1998 through June 30, 1999). In the first year, few providers completed applications for the discount, because most found they could not benefit from it under the original program.

Since the first year, the FCC has adopted a number of reforms to the program, which streamlines the discount application process,

<sup>5</sup> FTC: *Privacy Online: Fair Information Practices in the Electronic Marketplace*, A Report to Congress, May 2000, p. 38.

and addresses practical concerns voiced by practitioners and others. (See Appendix 5 for a detailed history of RHCD and OAT's FCC filing on Universal Service or at <http://telehealth.hrsa.gov/pubs.htm>). Funding in the second year of the program, after reforms were implemented, increased to \$6.1 million. Moreover the FCC and USAC expect that third year funding will increase to nearly \$10 million, once all reforms have been in place for a full year.

### **RESEARCH AND EVALUATION**

Few statistically significant studies of patient/physician satisfaction or telemedicine cost savings have been conducted. This dearth of research may be due to the relatively small number of telemedicine consultations in any one specialty and/or to the lack of a standard evaluation methodology to study either efficacy or patient/physician satisfaction across small groups of specialties and projects.

Despite the lack of statistical significance in most of the studies, all showed high patient satisfaction with telemedicine. Provider satisfaction was more variable, but generally moderate to high. Moreover, although one cannot generalize to all telemedicine applications, studies of specific services, such as tele-homecare and teledermatology, suggest that at least for these services, there may be real cost savings to be realized.

### **EMERGING TRENDS & POLICY ISSUES**

Two important trends that may greatly affect the telehealth industry and raise key policy issues are rapid technology changes and America's aging population. Shown on the next page are technology trends that already exist and will most likely be common in the near future.

In addition to technological trends, demographic trends will have an important impact on the health and telehealth industry. The aging of the Baby Boomer generation combined with a

longer life expectancy, will most likely mean a large population of "fragile" and chronically ill elderly, many of those requiring rehabilitation after hospitalization. Given this demographic trend, alone with the strong movement toward home health care, telehomecare will be an important associated trend. According to recent studies and workshops<sup>6</sup>, home care medical devices were the fastest growing segment of the medical device industry throughout the 1990s.

Providing tele-home care to the elderly or disabled populations, using telemedicine, raises important policy questions about health care access and the reimbursement of telemedicine services for both rural and urban patients. It can be argued that urban patients who are very elderly, chronically ill, poor or disabled may be as isolated and have as much difficulty getting access to needed health services as those living in rural areas. Most of these urban patients cannot drive to local clinics and many require assistance getting from point A to point B. Traveling a mile for such an urban patient may be as onerous as a rural patient's two hundred-mile drive to see a specialist.

Reimbursement for both rural and urban patients may be a cost effective policy decision. Studies show tele-homecare can save money by decreasing unnecessary hospital and emergency room admissions. Around the clock monitoring and nurse availability via videoconferencing has helped patients better self-diagnose and maintain drug therapies on schedule.

This policy issue may be resolved at the third party payer level, if cost savings are sufficiently great enough to attract the attention of this group.

<sup>6</sup> "Future Trends in Medical Device Technology: Results of an Expert Survey," FDA, April 1998 and Workshop on Home Care Technologies for the 21st Century, Catholic University, April 1999.

## NEXT STEPS

Outlined below are some proposed “next steps” for the Office for the Advancement of Telehealth (OAT) and the Joint Working Group on Telemedicine (JWGT).

### PAYMENT

- OAT will collaborate with HCFA, state Medicaid programs, private third party payers and other relevant organizations to create a forum in which the telemedicine experiences of third party payers can be shared.
- OAT will continue to refine its telemedicine scoring models for a broad range of telemedicine applications.

### LEGAL ISSUES

- The JWGT will work with various state governmental and professional groups to assess the feasibility of developing common licensure application forms, similar to the common college application form accepted at a number of universities. Common applications will reduce time and costs associated with completing numerous different applications that vary in state requirements and paperwork. States, in turn, can more easily develop a comprehensive database of practitioners and track them across state borders.

### SAFETY AND STANDARDS

- The OAT will work with its grantees, the American Telemedicine Association (ATA) and other groups to expand its clinical and technical guidelines. (See <http://telehealth.hrsa.gov/pubs.htm> for currently completed telemedicine application guidelines).
- OAT will continue to support the work of the Advanced Technology Institute, which is developing a Telehealth Deployment Re-

search Testbed. This work is being conducted in conjunction with the Medical University of South Carolina, West Virginia University Concurrent Engineering Research Center, Arthur D. Little, Oak Ridge National Laboratory, the Low country Healthcare Network and the CPRI-HOST consortium. The testbed will evaluate the effectiveness and practical utility of telehealth technologies by providing both laboratory and “real-world” evaluations.

- Medical Error reduction: OAT will develop a series of measures to be included in GPRA data elements to be collected by all OAT grantees.

### PRIVACY, SECURITY AND CONFIDENTIALITY

- OAT together with the Office for the Assistant Secretary of Policy and Evaluation have funded a research paper on “Privacy, HIPAA and Telemedicine” as well as a conference on the same subject. OAT and OASPE anticipate that the final paper and conference will be completed by summer 2001 and the results made available to the public both in print and on OAT’s Web site, shortly thereafter.

### TELECOMMUNICATIONS INFRASTRUCTURE

- OAT recently filed comments with the FCC on the question of “possible impediments to deployment and subscribership in unserved and underserved areas of the nation.” (See OAT’s FCC filing on Pacific Basin at <http://telehealth.hrsa.gov/pubs.htm>) Follow-up with the FCC on this issue continues.
- OAT also filed comments on the FCC’s proposal to set aside spectrum for the use of Wireless Medical Telemetry (See <http://telehealth.hrsa.gov/pubs.htm>). OAT’s comments also reflected



TECH TRENDS	TELEHEALTH APPLICATIONS	RELATED POLICY ISSUES
Internet	Most telehealth transactions may be done over the next generation Internet in video, voice, text, still images etc.: on-line consultations, prescription purchases and administrative transactions.	<ul style="list-style-type: none"> <li>• Retrofitting HIPAA and other privacy concerns</li> <li>• Blurring of borders and scope of practice</li> <li>• Security issues</li> </ul>
Digitization	Smart cares, digital medical libraries, compressed video and images, imbedded chips.	<ul style="list-style-type: none"> <li>• Interoperability</li> <li>• Information interexchange</li> <li>• Technical standards</li> </ul>
Wireless Technology	<p>Hand held computers, mobile videophones, and satellite based mobile hand held devices with global access.</p> <p>Emergency medical applications such as two-way video consultations.</p> <p>Wireless monitoring in the home. Other home wireless equipment with two way video and peripherals for blood pressure, heart rate, etc. Biosensors, data feedback loop.</p>	<ul style="list-style-type: none"> <li>• Electromagnetic Interference</li> <li>• Future spectrum bandwidth needs</li> <li>• Interoperability across equipment</li> <li>• Interconnection problems</li> <li>• Security issues</li> </ul>

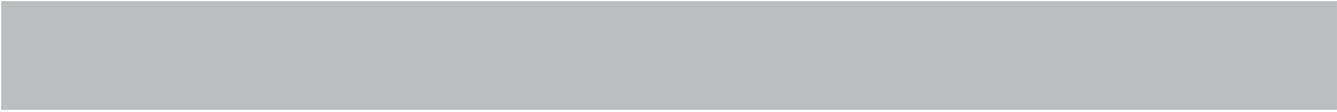
concern about adequate spectrum for future telemedicine applications, which may require more bandwidth than currently allocated for telemetry. This issue will most likely remain an issue in the near future.

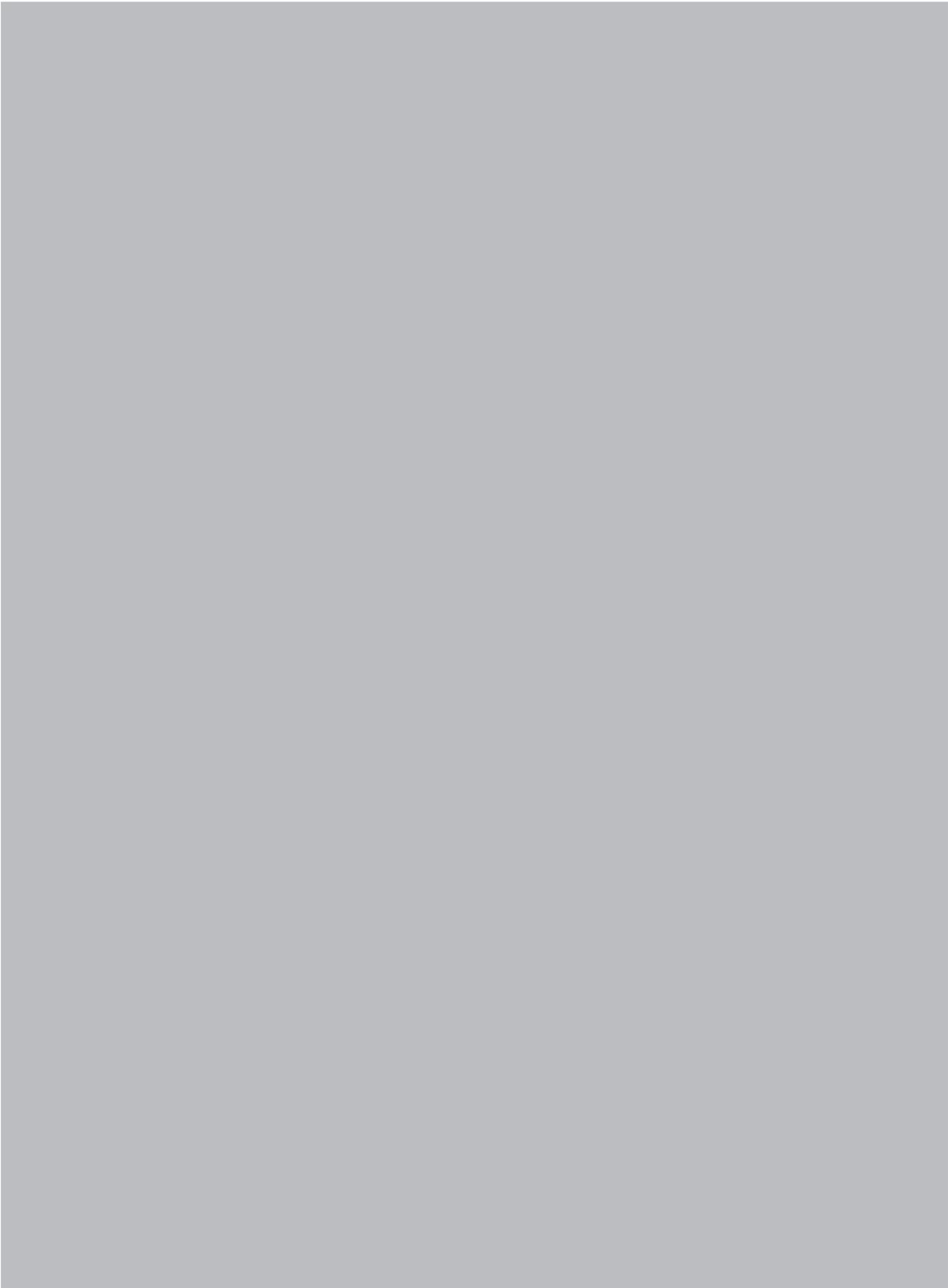
**RESEARCH AND EVALUATION**

- OAT will collaborate with other Agencies within HHS as well as work with JWGT members to develop an evaluation stra-

tegy that uses cross-project evaluation methodologies to obtain more generalizable findings.

- Future evaluations should examine provider satisfaction, quality and cost implications of telemedicine for specific applications such as telehome-care, tele-dermatology and mental health.





# Introduction

## OVERVIEW

The beginning of the new millennium is a time to look back from where we have come and to dream of where we wish to go. For those in health care, the scientific triumphs of the past, such as the eradication of polio and small pox or the development of immunization, point to a future, when closing the health gap between the “haves and have nots” in this country and throughout the world, is possible.

Imagine a world, where no matter who you are or where you are you get the health care you need, when you need it. Such a dream could already be a reality. Technologies such as interactive videoconferencing, the Internet, store-and-forward imaging, streaming media, satellite and other wireless communications networks already exist and can deliver health services or education over vast distances. However, these are not yet part of the landscape for our nation’s rural and urban underserved peoples.

Although these technologies are available, several barriers, such as the lack of significant reimbursement, cross-state licensure problems, privacy issues, lack of universal standards and high transmission costs, have inhibited the telemedicine and telehealth industry from reaching its full potential in the United States.

In addition to these traditional barriers, the dramatic growth and use of the Internet by health consumers poses new challenges. Despite its great benefits, such as a wealth of health information or fingertip access to prescription drugs, the Internet has created serious threats to industry expansion. These include new legal, safety, privacy and confidentiality concerns for the telemedicine industry.

The Healthcare Research and Quality Act of 1999, Section 6, requires the Secretary of Health and Human Services (HHS) to submit this Report to

Congress on Telemedicine, no later than January 10, 2001. Congress requested that the Report describe barriers to telemedicine, determine the extent of patient and physician satisfaction with this mode of health delivery and evaluate the extent to which patients have benefitted from telemedicine services.

What exactly is meant by telemedicine and telehealth? In the Department of Commerce’s 1997 Report to Congress, “telemedicine” referred to “the use of electronic communication and information technologies to provide or support clinical care at a distance.”<sup>1</sup> Telehealth is a broader concept than telemedicine. For the purposes of this Report, it is defined as the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration.

## CURRENT TRENDS

One of the most important trends to emerge over the past five years is the remarkable growth and development of the Internet. While much of this report focuses on telehealth providers and the barriers they face in expanding the delivery of telehealth, that is only part of the story. The Internet is dramatically changing the way consumers access health information, receive diagnostics and purchase pharmaceuticals. It is also conceivable that soon health providers will move much of their administrative transmissions onto the Internet. Hence, the Internet may greatly affect different aspects of telemedicine and telehealth.

According to the Federal Trade Commission (FTC), consumer online searches for health information are increasing dramatically. Thirty million Americans are expected to seek health

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<sup>1</sup>1997, *Telemedicine Report to Congress*, U.S. Department of Commerce, P.1.

information online by 2001.<sup>2</sup>

To establish a viable presence on the Internet, the banking, credit card and retail industry, among others, have found it critical to reassure their consumers about the protection of personally identifiable information. Although online shopping, banking and auction bidding are ubiquitous, what consumer does not worry about the random stealing of information by computer hackers? More insidious is the possibility that entire identities can be stolen after a person's social security and other personal information has been made public on the Internet.

Just as other industries have found the Internet to be both a market boon and privacy bane, so the health industry may find that consumers of health information, prescriptions or other health services on the Internet, may be vulnerable. As the Georgetown University Health Privacy Project notes:

*“Although health Web sites now provide a wide range of clinical and diagnostic information; opportunities to purchase products and services; interactions among consumers, patients, and health care professionals; and the capability to build a personalized health record, they have not matured enough to guarantee the quality of the information, protect consumers from product fraud or inappropriate prescribing, or guarantee the privacy of individuals’ information.”*

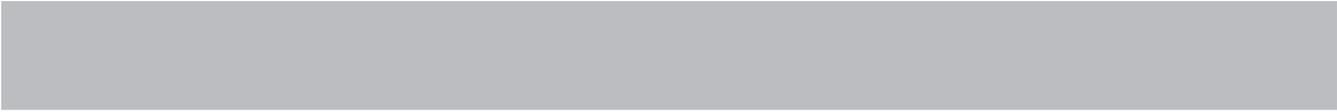
### **STRUCTURE OF THE REPORT**

The structure of the Telemedicine Report to Congress, 2001 is similar to that of the 1997 Report. Chapter III describes the current Medicare reimbursement rules for telemedicine, as well as the preliminary outcomes for the first year of this program. Chapter IV discusses legal issues affecting the proliferation of telemedicine and telehealth, including state licensure and electronic health information issues as well as other related issues,

such as credentials. Chapter V outlines safety and standards issues, limited to specific telehealth concerns. Chapter VI highlights HHS privacy rules for personally identifiable health related information that is electronically stored or transferred. This chapter also discusses how these proposed rules may affect telehealth practitioners. Chapter VII examines the Federal Communications Commission's (FCC) Universal Service Administrative Company's (USAC) Rural Health Care Program. This Chapter also highlights recent FCC reforms that address some telehealth practitioner concerns that were major barriers to applying to the program. Chapter VIII draws upon previous research to summarize the current status of patient and physician satisfaction with telemedicine and anecdotal examples of telemedicine efficacy. The final Chapter IX looks at issues that may emerge over the next few years. Specifically Congress requests that HHS report the following:

- The extent to which patients receiving telemedicine services have benefitted from them and are satisfied with the treatment received pursuant to the services;
- The extent to which medical outcomes for such patients would have differed if telemedicine services had not been available to them;
- The extent to which physicians involved with telemedicine services have been satisfied with the medical aspects of the services; and
- The extent to which primary care physicians are enhancing their medical knowledge and experience through the interaction with specialists provided by telemedicine consultations.

<sup>2</sup>Federal Trade Commission, *Protecting Consumers Online: A Federal Trade Commission Report on the First Five Years of Its Internet Law Enforcement Program*, December 1999.





# Payment Issues

## OVERVIEW

One of the greatest stumbling blocks to the expansion of the telehealth industry has been lack of reimbursement for telemedicine and telehealth services. Advances in telemedicine technology have made it easy to deliver health care services over a distance but few public or private payers will pay telemedicine costs. Until recently, Medicare has not had an explicit policy to pay for telemedicine services. Historically, Medicare reimbursed some services that did not traditionally require face-to-face contact between a patient and practitioner. For example, it covered EKG or EEG interpretation, teleradiology and telepathology in most of the nation, depending on individual Medicare carrier policies.

However, the Balanced Budget Act of 1997 (BBA) brought about a significant change in Medicare telemedicine reimbursement policy. As of January 1, 1999, Congress required the Health Care Financing Administration (HCFA), DHHS to pay for telemedicine consultation services under the BBA. Some current reimbursement eligibility requirements are outlined in Table 1.

## MEDICARE REIMBURSEMENT— THE FIRST TWO YEARS

Over the first two years of the Medicare telemedicine reimbursement rule, many telehealth practitioners have found both the BBA mandates and HCFA's interpretation of the BBA too narrow for most practical purposes. On September 30, 2000, after almost two years of telemedicine reimbursement, Medicare has reimbursed a total of \$20,000 for 301 teleconsultation claims.

Four major issues may have greatly limited the number of reimbursable telemedicine consultations:

- **Health Professional Shortage Area Limitations.** Only patients in Health Professional Shortage Areas (HPSAs)

were eligible for reimbursement under the BBA. This restriction greatly narrows the number of people, who might benefit from telemedicine, and disregards the needs of many rural patients, who may have access to a nurse or general practitioner, but not to specialists such as cardiologists, psychologists, dermatologists, etc.

- **Fee-sharing requirement.** Consulting physicians found fee-sharing problematic because they received only 75 percent of normal pay for their services. Moreover, HCFA reports consultant payment to the IRS at 100 percent. Other problems with fee-sharing included accounting and fee tracking. Most rural practitioners are not equipped to track split fees. Finally, perhaps the most important ramification of the fee-sharing requirement is that, to be paid, the eligible presenter must either be the referring physician or an employee of the referring physician. In many cases, the presenter is an employee of the local hospital or clinic.
- **Eligible presenters.** In many (if not most) places rural clinics are staffed only by registered nurses (RNs), licensed practical nurses (LPNs) or by health technicians, who were all ineligible presenters under the BBA. In a survey of 20 telehealth networks representing 4,761 telehealth encounters between Jan. 1, 1999 and June 30, 1999, the University of Missouri found that:
  - *LPNs and RNs make up the majority of patient presenters in almost all telehealth networks, but they are not eligible presenters.*
  - *171 or 3.6% of all encounters involved a patient interaction with either an occupational, physical, speech therapist or*

**Table 1: TELEMEDICINE REIMBURSEMENT REQUIREMENTS**

(Under the Medicare, Medicaid & SCHIP Benefits & Improvement Protection Act of 2000)

SCOPE	ELIGIBILITY REQUIREMENTS
GEOGRAPHIC SCOPE	Only patients located in Rural Health Profesional Shortage Areas (HPSAs), counties in Non-MSAs and in approved Federal demonstration projects are eligible for telemedicine reimbursement. A list of HPSA shortage areas can be found at <a href="http://www.access.gpo.gov">http://www.access.gpo.gov</a> .
ELIGIBLE SERVICES/ CPT CODES	Eligible Current Procedural Terminology (CPT) codes include professional consultations, office visits, and office psychiatry services (codes 99241-99275; 99201-99215; 90804-90809; and 90862) and any additional services specified by the Secretary.
ELIGIBLE PRESENTING PRACTITIONER	The new law eliminates the requirement to have a telehealth presenter present a patient at a consultation unless it is medically necessary (as determined by the physician or practitioner at the distant site).
FEE-SHARING	The new law eliminates the fee sharing requirement between a consultant and referring physician.
ELIGIBLE TECHNOLOGY <sup>1</sup>	The new Act provides for reimbursement for store and forward technology in demonstration projects in Alaska and Hawaii but no other setting. HCFA’s payment policy was developed to replicate a standard consultation as closely as possible. Under Medicare, a separate payment for a consultation requires a face to face examination of the patient. This requirement is consistent with the American Medical Association’s description of a consultation. To that end, Medicare’s teleconsultation rule requires a certain level of interaction between the patient and consulting practitioner because it offers the best substitute for a “face to face” consultation. Regardless of the technology, the patient must be present during the consultation.
HOME HEALTH CARE	The new Act clarifies that home health agencies “may adopt telehealth technology that it believes promotes efficiencies or improves quality of care, however, these technologies will not be specifically recognized or reimbursed under the home health benefit. Telehealth encounters do not meet the definition of a Medicare covered home health visit. But this does not preclude a home health agency from spending prospective payment dollars to furnish services outside of the Medicare home health benefit (i.e. for telehealth services to home health beneficiaries). If a physician intends that telehealth services be furnished while a patient is under a home health program of care, this should be recorded in addition to the Medicare covered home health services to be furnished.”

<sup>3</sup> Medicare has historically reimbursed some telemedicine services that did not traditionally require face-to-face contact between a patient and practitioner. For example, Medicare covered EKG or EEG interpretation, teleradiology, and telepathology in most areas of the nation, in accordance with individual Medicare carrier policies.

clinical psychologist.  
– Only 7% of referring of the referring practitioner acted as patient presenters in consultations. This suggests that if all of the reported 4,761 telehealth activities were Medicare, less than 7 percent of all cases would meet HCFA's eligible presenter criteria.

- **Eligible Current Procedural Terminology Codes:** Only a few codes were eligible for HCFA telemedicine reimbursement. This limitation greatly restricted the types of services for which practitioners could be reimbursed. Many services that telemedicine providers already offer were not included in these codes.

## LEGISLATION

The House and Senate introduced nine bills with telehealth provisions in the 106<sup>th</sup> Session to address the BBA's telemedicine reimbursement limitations and to allow more Medicare coverage for telemedicine services. At the end of December 2000, Congress passed the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("the Act"), which becomes effective October 1, 2001. (See Table 1)

Among other things, Section 223 of the Act, eliminates the presenter and fee-sharing requirements, expands eligible locations to include HPSAs and counties not included in a Metropolitan Statistical Area, expands the number of CPT codes that are eligible for Medicare reimbursement and provides full reimbursement to a specialist for services rendered in a teleconsultation. Section 503 addresses the use of telehealth in the delivery of home health

services. (See Appendix 1 for language of the Act and a comparison of the bills)

Historically, one of the key challenges to the passage of any expansion of telemedicine reimbursement has been the lack of data upon which to judge its impact on government expenditures. The Office for the Advancement of Telehealth (OAT) has worked with the Center for Telemedicine Law (CTL) and OAT's grantees to develop a series of cost models that would provide a more accurate estimate of the impact of expanded coverage on third party payers. These "scoring" models have the advantage of being able to use actual telemedicine experience from the field. Preliminary results suggest that many of the modest telemedicine reimbursement expansions introduced in the 106<sup>th</sup> Congress would have minimal impact on Medicare expenditures. (For example, CTL/OAT estimates of Senate Bill 2505 budgetary impact range from \$50 to \$100 million over five years as compared to an estimate of over a billion dollars scored for legislation in earlier years.)

## OTHER PAYMENT COVERAGE

In addition to Medicare payments for telemedicine, 20 state Medicaid programs as shown in Box 1 and several state Blue Cross/Blue Shield plans, as well as some other private insurers, pay for select telemedicine services. Several states have recently passed laws that prohibit insurers from discriminating between regular medical and telemedicine services' reimbursement. These states include California, Texas and Louisiana.

Some private insurers also provide limited telemedicine coverage in certain states. For

### BOX 1 MEDICAID

#### STATE COVERAGE

Arkansas, California, Georgia, Iowa, Illinois, Indiana, Kansas, Kentucky, Louisiana, Montana, Nebraska, North Carolina, North Dakota, South Dakota, Oklahoma, Texas, Utah, Virginia, and West Virginia. In addition, Connecticut, Maine and Minnesota are piloting telemedicine programs.\*

Sources: CTL "Medicaid Telemedicine and Telehealth Update", July 2000, Health Care Finance Administration <http://www.hcfa.gov/medicaid/telemed.htm>

\* Sources: CTL "Medicaid Telemedicine and Telehealth Update", July 2000, Health Care Finance Administration, DHHS

example, Blue Cross-Blue Shield in Montana and North Dakota provide some telemedicine coverage and Blue Cross of California is going a step further by developing a statewide telemedicine network. In July 1999, the Managed Risk Medical Insurance Board awarded \$1.8 million to Blue Cross California to expand telemedicine capabilities throughout California. Blue Cross planned to use the funds to expand services at 17 existing clinics to serve medically underserved populations and to provide equipment and support to 22 new telemedicine sites in 18 counties.

#### **NEXT STEPS**

- OAT will collaborate with HCFA, state Medicaid programs, private third party payers and other relevant organizations to create a forum in which the experiences of third party payers with telemedicine can be shared.
- OAT will continue to refine its telemedicine scoring models for a broad range of telemedicine applications.



# Legal Issues

## OVERVIEW

Five years ago, interstate licensure issues were thought to be among the most critical barriers to telemedicine. Today, the problem has been compounded by the growth and consumer use of the Internet. The Internet has also raised new legal issues that may grow to overshadow interstate licensure.

Since the Department of Commerce's 1997 Report to Congress on Telemedicine was published, the problem of multiple state licensure requirements for telemedicine providers has not improved and in some ways has worsened. Since then, more states have adopted restrictive laws requiring out-of-state telemedicine practitioners to obtain local state medical licenses.

## STATE MEDICAL LICENSURE AND LICENSURE MODELS

Historically, states have had the authority to regulate activities affecting the health, safety and welfare of their citizens. Hence, health professionals

in the United States are licensed at the state level. States define the process and procedures for granting a health professional license, renewing a license and regulating medical practice within the state. The Federal government does have the authority to establish national regulations such as those under Medicare that set specific eligibility requirements for reimbursement. However, there is a strong legal presumption against federal preemption of state licensure laws. Therefore, unless Congress acts to regulate telemedicine licensure, the states themselves must decide to harmonize their standards and laws. Tables 1, 2 and 3 illustrate generic and specific licensure models that could be used for multiple state health licenses.

## PHYSICIAN AND NURSE STATE LICENSURE FOR TELEMEDICINE PRACTICE

In early 1997 only 11 states had telemedicine licensure laws. Today, about 26 states have introduced licensure laws pertaining specifically to telemedicine that may make it more difficult for

## Table 2: GENERIC LICENSURE MODELS

### CONSULTING EXCEPTIONS

With a consulting exception, a physician who is unlicensed in a particular state can practice medicine in that state at the request of and in consultation with a referring physician. The scope of these exceptions varies from state to state. Most consultation exceptions prohibit the out-of-state physician from opening an office or receiving calls in the state. In most states, these exceptions were enacted before the advent of telemedicine and were not meant to apply to on-going regular telemedicine links. However, some states permit a specific number of consulting exceptions per year. Hawaii, Colorado and California allow significant consulting exceptions.

### ENDORSEMENT

State boards can grant licenses to health professionals in other states with equivalent standards. Health professionals must apply for a license by endorsement from each state in which they seek to practice. States may require additional qualifications or documentation before endorsing a license issued by another state. Endorsement allows states to retain their traditional power to set and enforce standards that best meet the needs of the local population. However, complying with diverse state requirements and standards can be time consuming and expensive for a multi-state practitioner.

**Table 2: GENERAL LICENSURE MODELS cont.**

RECIPROCITY	A licensure system based on reciprocity would require the authorities of each state to negotiate and enter agreements to recognize licenses issued by the other state without a further review of individual credentials. These negotiations could be bilateral or multilateral. A license valid in one state would give privileges to practice in all other states with which the home state has agreements.
MUTUAL RECOGNITION	Mutual recognition is a system in which the licensing authorities voluntarily enter into an agreement to legally accept the policies and processes (licensure) of a licensee's home state. Licensure based on mutual recognition is comprised of three components: a home state, a host state and a harmonization of standards for licensure and professional conduct. The health professional secures a license in his/her own home state and is not required to obtain additional licenses to practice in other states. The nurse licensure compact is based on this model.
REGISTRATION	Under a registration system, a health professional licensed in one state would inform the authorities of other states that s/he wished to practice part-time there. By registering, the health professional would agree to operate under the legal authority and jurisdiction of the other state. Health professionals would not be required to meet entrance requirements imposed upon those licensed in the host state but they would be held accountable for breaches in professional conduct in any state in which they are registered. California has the authority to draft this type of model.
LIMITED LICENSURE	Under a limited licensure system, a health professional would have to obtain a license from each state in which s/he practiced but would have the option of obtaining a limited license for the delivery of specific health services under particular circumstances. Thus, the system would limit the scope rather than the time period of practice. The health professional would be required to maintain a full and unrestricted license in at least one state. The Federation of State Medical Boards has proposed a variation of this model.
NATIONAL LICENSURE	A national licensure system could be adopted on the state or national level. A license would be issued based on a universal standard for the practice of health care in the U.S.. If administered at the national level, questions might be raised about state revenue loss, the legal authority of states and logistics about how data would be collected and processed. If administered at the state level, these questions might be alleviated. States would have to agree on a common set of standards and criteria ranging from qualifications to discipline.
FEDERAL LICENSURE	Under a Federal licensure system health professionals would be issued one license, valid through the U.S., by the Federal government. Licensure would be based on Federally established standards related to qualifications and discipline and would preempt state licensure laws. Federal agencies would administer the system. However, given the difficulties associated with central administration and enforcement, the states might play a role in implementation.

Source: U.S. Department of Commerce, "Report to Congress on Telemedicine," 1997.

**Table 3: SPECIFIC LICENSURE MODELS**

AMERICAN COLLEGE OF RADIOLOGY (ACR)	In 1994, the ACR adopted a “Standard for Teleradiology” and developed a Model Act based on this standard that is similar to the general endorsement model described above.
AMERICAN MEDICAL ASSOCIATION (AMA)	In 1994, the AMA adopted a policy that “states and their medical boards should require a full and unrestricted license for all physicians practicing telemedicine within a state.”
CALIFORNIA STATE REGISTRATION	The State of California’s law is a specific example of a registration model. In 1997, California passed laws that permits the Board of Medicine to create a registration program for telemedicine providers.
COLLEGE OF AMERICAN PATHOLOGISTS (CAP)	The CAP model is a variation of the endorsement model. This proposal requires physicians to have their licenses endorsed in each state from which they receive patient specimens of information. The CAP suggests that an abbreviated licensure process would be preferable to a license for limited practice.
FEDERATION OF STATE MEDICAL BOARDS (FSMB)	The FSMB supports a special licensure for telemedicine, a variation on the general limited licensure model. In 1995, FSMB proposed an “Act to Regulate the Practice of Medicine Across State Lines.” Under this Act, a physician would be required to obtain a special license issued by the state medical board. Several states have adopted variations on this model including Alabama, Tennessee and Texas.
NATIONAL COUNCIL OF STATE BOARDS OF NURSING (NCSBN)	The National Council’s model is the most far reaching of any model and is based on the general mutual recognition model. In November 1998, the National Council adopted language for an Interstate Nurse Licensure Compact. This compact creates a unified standard for nurses’ licenses. Nurses will be able practice telemedicine in whichever states adopt the compact. Licenses will be fully recognized by the host and home state by mutual recognition. To date, Arkansas, Delaware, Iowa, Maine, Maryland, Mississippi, Nebrasks, North Carolina, South Dakota, Texas, Utah and Wisconsin have passed this compact into law.

Source: U.S.Department of Commerce, “Report to Congress on Telemedicine,” 1997.

physicians to practice telemedicine across state lines. Appendix 2 lists these states. Making it easier for nurses to practice across state lines, the National Council of State Boards of Nursing (NCSBN) developed a licensure model based on mutual recognition called the Interstate Nurse Licensure Compact. As described in Box 2, NCSBN promotes the introduction of legislation and the adoption of state laws to allow nurses to practice across state borders without being licensed outside their home states. Currently, 12 states have adopted the Nurse Licensure Compact as listed in Box 3. Other organizations, such as the National Association of Pediatric Nurse Associates, and Practitioners, and the Association of Women's Health, Obstetric and Neonatal Nurses, believe that alternative models like the national licensure model, as described in Table 2, and in their letter in Appendix 3 may be a better solution.

**LEGAL ISSUES RELATING TO THE INTERNET**

Consumers with access to the World Wide Web can peruse volumes of health information, join chat groups, purchase pharmaceuticals in privacy and consult a health care practitioner for a fee. But together with these benefits, the Internet has added new twists to old licensure problems and has raised other legal issues. For example, given the nature of the Web, it may be difficult for a consumer or

**BOX 2**

**INTERSTATE NURSES LICENSURE COMPACT**

**Under this compact, the head of the nursing licensing board will administer the Compact for his/her state. Among other things, this compact states that:**

*“License to practice registered nursing issued by a home state to a resident in that state will be drecognized by each party state as authorizing a multi-state licensure privilege to practice as a registered nurse in such party state.”*

**This compact also applies to a license to practice licensed practical/vocational nursing. To coordinate these multi-state licenses, all party states:**

*“shall participate in a cooperative effort to create a coordinated data base of all licensed nurses and licensed practical/vocational nurses.”*

**Including information on a nurse’s licensure and disciplinary history.**

**BOX 3**

**STATE THAT ADOPTED THE COMPACT**

**Arkansas, Delaware, Iowa, Maine, Maryland, Mississippi, Nebraska, North Carolina, South Dakota, Texas, Utah and Wisconsin**

state government to determine whether or not particular Web sites comply with states’ laws pertaining to a physician’s or other health practitioner’s interstate practice. Theoretically, on-line health practitioners, who do not provide specific medical advice or diagnosis, would probably not be seen as practicing medicine across state lines. Realistically however, these consultations can fall into large gray areas.

Perhaps the larger legal issue for many states may be their ability to enforce their own state health laws. For example, if a consumer, located in state A, sues an on-line practitioner, based in state B, who has jurisdiction in this case? Does the jurisdiction change if the interactive consultation was accomplished via the Web, over the telephone, via email or a two-way teleconferencing unit? What happens if the Web site was created and staffed outside the United States? What recourse would the consumer have if the Web site was immediately

taken down but reconfigured under a different address the next day?

These legal questions apply not only to Web based companies but also to companies that provide health care consultations using any type of technology across state borders. For example, many health insurance companies now give their clients the option to consult with a nurse over the telephone before seeking face-to-face medical consultation. Large

health insurance companies with a national base will often subcontract to a company with a central office staffed with nurses, who field incoming nationwide calls. Do these nurses need to be licensed in every state in order to answer these calls?

A recent HHS report: *Wired for Health and Well-Being*, (<http://www.scipich.org>) states that “the extent and nature of liability associated with IHC (Interactive Health Communication) applications are unclear. Providing medical advice through IHC applications, including Web sites, increases potential liability for developers. To what extent the developers, sponsors, content providers, or others involved in the design and implementation of the application will be liable for damages is unknown. In the absence of precedents in this area, future legal action and case law may provide some clarity on these issues.” (Wired for Health and Well-Being, HHS, Office of Public Health and Science, April 1999)

Finally, whether Web developers are state certified or not, the issue of illegal drugs sold over the Internet or legal drugs sold without an initial patient examination by a physician has created a growing safety and legal challenge for both state and federal regulators, as discussed in the next chapter.

### **OTHER RELATED ISSUES**

Another dilemma that has not been resolved is whether or not health care practitioners providing telehealth services should be certified in this area. Earlier this year, the Joint Working Group on Telemedicine (JWGT) developed a draft discussion paper (See Appendix 4), exploring the advantages and disadvantages of certification. According to the paper, there is confusion about the meaning of the term. Credentialing, certification, privileging and licensing are often used interchangeably to describe the validation of practitioners’ competencies in

telehealth. National professional and provider organizations and government agencies are increasingly queried about whether there is a need for additional and/or official validation of practitioners’ competency to engage in telehealth. And it is unclear whether the questions about validation relate either solely to the equipment used or to the clinical care delivered. Additional complexity surrounds the relationship of the validation of individuals versus organizations.

The JWGT hopes to compile comments about the draft paper from interested parties and provide a summary of its findings.

Although little has been resolved about individual accreditation, there has been change at the institutional level. In the fall of 2000, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), an independent, not-for-profit organization, adopted new credentialing standards for hospitals using telemedicine. The full text of these new standards, which become effective January 1, 2001, can be found at [http://www.jcaho.org/standardmedicalstaff\\_rev.html#Telemedicine](http://www.jcaho.org/standardmedicalstaff_rev.html#Telemedicine). JCAHO evaluates and accredits nearly 20,000 health care organizations and programs in the United States. Its accreditation is recognized nationwide as a symbol of quality that indicates that an organization meets certain performance standards. To earn and maintain accreditation, an organization must undergo an on site survey by a JCAHO survey team at least every three years.<sup>4</sup> The new standards amend medical staff standards within the accreditation manual for hospitals. According to the manual:

“If a telemedicine practitioner prescribes or renders a diagnosis, or otherwise provides clinical treatment to a patient, the telemedicine

<sup>4</sup>Information about JACHO was taken from their website at <http://www.jcaho.org>

practitioner is credentialed and privileged by the organization receiving the telemedicine service. An organization may use credentialing information from another Joint Commission accredited facility, so long as the decision to delineate privileges is made at the facility that is receiving the telemedicine service.”

#### **NEXT STEPS**

- The Joint Working Group on Telemedicine will work with various state governmental and professional groups to assess the feasibility of developing common licensure

application forms, similar to the common college application form, accepted at a number of universities. Common applications will reduce time and costs associated with completing numerous different applications that vary in state requirements and paperwork. States, in turn, can more easily develop a comprehensive database on practitioners and track them across state borders.



# Safety and Standards

## OVERVIEW

Thanks to advances in technology, telemedicine practitioners have shifted easily from the phone to the personal computer to the Internet to wireless handheld devices. Yet, the full potential of these advances cannot be reached without clinical and technical standards and guidelines.

In the past few years, the need for standards has taken on greater importance, not only in the world of telemedicine, but also in the world at large. Without widely adopted standards and guidelines, interoperability and interconnection are not possible and the great potential of telemedicine will be difficult to achieve. Older equipment often will not connect with newer versions of the same machine; different brands do not operate with one another, making networking across projects and sometimes within a project expensive and frustrating.

In addition to technical standards, clinical protocols and guidelines are needed. Clinical protocols for telemedicine practice include preliminary scheduling procedures, actual consult procedures and telemedicine equipment operation procedures (such as telecommunications transmission specifications). The clinical technical standard for image quality in a video transmission would specify the technical standards needed by a specialist such as a dermatologist to achieve the high levels of image clarity and color required to correctly diagnose a patient.

Unlike most clinical health professional groups, U.S. telemedicine practitioners have not formally developed and adopted many clinical protocols or technical standards for telehealth applications. However, a few professional associations have adopted some clinical practice protocols.

- The American Telemedicine Association recently adopted Telehomecare Clinical

Guidelines, posted on their Web site at <http://www.atmeda.org/news/guidelines.html>. Additionally, the Association has posted a May 1999 working draft of its Clinical Guidelines for Telepathology.

- The American Psychological Association has posted clinical guidelines on its Web site to guide in the practice of telepsychiatry
- The American Dermatology Association has drafted proposals for clinical protocols for teledermatology.
- The American Nurses Association, assisted by the Interdisciplinary Telehealth Standards Working Group, developed the “Core Principles on Telehealth” in March 1998 and “Competencies in Telehealth Technologies in Nursing in March 1999.

The following is a short list of technical standards and guidelines that have been adopted or have been proposed that relate directly or indirectly to telemedicine and telehealth.

- The American College of Radiology and the National Electronic Manufacturers Association created a uniform set of communication standards called DICOM (Digital Imaging and Communications in Medicine).
- HL 7:<sup>5</sup> standard for data exchange. The most widely used HL7 specification is the Application Protocol for Electronic Data Exchange in Healthcare Environments. This is a messaging standard that enables disparate healthcare applications to exchange data.
- Kennedy-Kassebaum Health Insurance

<sup>5</sup>Health Level Seven is one of several ANSI-accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. Health Level Seven's domain is clinical and administrative data.

Portability and Accountability Act of 1996 (HIPAA) mandated the development and adoption of standards for electronic exchange of health information for administrative purposes. As of December 2000 DHHS released its final rules on privacy practices for eligible entities such as health plans, clearing house and providers who engage in electronic transactions.

- OAT and the JWGT organized a workshop in September 1999 to address the need for guidelines in the area of technical standards for telemedicine practice. Several guidelines have already been completed for telecardiology, teledermatology, telerehabilitation, teleophthamology and telepsychiatry. (See: <http://telehealth.hrsa.gov/pubs.htm>) Additionally, OAT has funded a grant to the Advanced Technology Institute to develop a technical assessment center. This Telehealth Deployment Research Test bed will establish a national distributed test bed that will evaluate the effectiveness and practical utility of telehealth technologies by providing laboratory and “real world” evaluations.

### **FDA REGULATORY ROLE**

Widely adopted standards and guidelines not only serve as a foundation for interoperability and interconnection but also to protect public health. The US Federal Food and Drug Administration (FDA) plays a critical regulatory role in ensuring the safety and effectiveness of telemedicine medical devices and software with the Center for Devices and Radiological Health (CDRH) acting as lead agency. This role was discussed at length in the Department of Commerce’s 1997 Report to Congress on Telemedicine (See Appendix 5).

Over the past five years, the FDA has continued its oversight of medical devices and software associated with telemedicine. It has developed

guidelines and provided assistance to industry and other regulators through the work of several telemedicine related working groups. For example, the Telemetry Working Group worked with the FCC to provide new spectrum for wireless medical service after digital TV signals interfered with wireless medical telemetry equipment in 1999. The Software Working Group has developed guidelines for software contained in Medical Devices and the Telemedicine Working Group has developed guidelines on Medical Image Management Devices, on Digital Mammography and Picture Archiving and Communications Systems and Related Devices. Given the growing importance of the home health industry, the FDA and the National Science Foundation cosponsored the “Workshop on Home Care Technologies for the 21st Century.” The FDA also recently approved Tele-homecare equipment for market. Current telemedicine related FDA guidelines can be found at the following sites:

- Guidance for the Submission of Premarket Notification for Medical Image Management Devices,(7/27/2000) <http://www.fda.gov/cdrh/ode/guidance/416.pdf>.
- Guidance for Industry: Wireless Medical Telemetry Risks and Recommendations (9/27/2000) <http://www.fda.gov/cdrh/comp/guidance/1173.html>
- FDA Talk Paper: FDA approves first digital mammography system. (1/31/2000) <http://www.fda.gov/bbs/topics/ANSWERS/ANS01000.html>
- ODE: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.(5/27/98) <http://www.fda.gov/cdrh/ode/software.pdf> or <http://www.fda.gov/cdrh/ode/57.html>
- MQSA Regulations relevant to new mammographic modalities are in 21CFR900: Quality Mammography Standards (as

amended): <http://www.fda.gov/cdrh/mammography/frmamcom2.html#12>

Another notable change in FDA's role in telehealth is its growing involvement in the oversight of relevant Internet activities. Over the past few years, some Web sites have offered illegal drugs or prescription drugs based on questionnaires rather than a face-to-face examination by a licensed sites offer prescription drugs with any prescription. The FDA is working with the National Association of Boards of Pharmacy (NABP), which created a program in 1999 called Verified Internet Pharmacy Practice Sites or VIPPS. The program gives consumers a single place to check out an online pharmacy to ensure that it meets current standards. To become certified by VIPPS, an online pharmacy must meet the licensing and inspection requirements in the state where it is located and in each state to which it dispenses pharmaceuticals. The FDA has also worked with the Federation of State Medical Boards on prescribing issues. The FDA's role in this area compliments that of the Federal Trade Commission, a key player in enforcement (*see below*). Moreover, states remain primarily responsible for regulating and licensing of health care providers and pharmacies. About 13 states have recently passed laws that require a physical examination before prescribing medication either over the phone or over the Internet as shown in Box 4.

#### **THE FTC, CONSUMERS & THE INTERNET**

A number of federal and state regulatory agencies are working together to address health-related consumer problems on the Internet. They include state health authorities, the Federal Food and Drug Administration, the Justice Department,

and the Federal Trade Commission. The Federal Trade Commission plays a key oversight and enforcement role in Internet Commerce as illustrated in its December 1999 Report: *Protecting Consumers Online: A Federal Trade Commission Report on the First Five Years of Its Internet Law Enforcement Program*. In this report the Commission discusses its activities to combat general consumer fraud and deception on the Internet. Since 1994, it has focused on the largest and "most egregious" fraud and deception examples, taking action against companies in more than 100 cases. As shown in Box 5, the Commission has made false or unsubstantiated health claims online a law enforcement priority.

Despite the actions of regulators, consumers must bear the major burden of determining the safety and privacy of health related Web sites that they use. Several US Government-sponsored Web sites for consumer health information are reviewed and links are carefully selected, with the selection criteria described on each site. Several years ago, DHHS introduced its Web based "Health Finder" - an Internet Website (<http://www.healthfinder.gov>) that provides search capabilities on health information. Healthfinder includes links to other important government health sources such as Medlineplus (<http://medlineplus.gov/>), created by the National Library of Health. Other links to the Center for Disease Control, the FDA and the National Cancer Institute name just a few of the myriad Federal government health information sources. While the Federal government has made credible health information more accessible to consumers on the Web, private and non-profit company Web sites have also proliferated. These health-oriented Web sites range widely from those providing general health

#### **BOX 4 STATES ENACTING LEGISLATION REQUIRING PHYSICAL EXAMINATION BEFORE PRESCRIBING MEDICATION**

**Alabama, Arizona,  
California, Florida,  
Iowa, Idaho,  
Kansas, Maine,  
Mississippi,  
Nebraska, New  
York, Ohio,  
Virginia**

information to those selling pharmaceuticals to those that provide a medical opinion for a fee.

For any such Web site, consumers may find it difficult to determine the “quality” of the site. Consequently, the DHHS’ national Healthy People 2010 initiative includes the goal of increasing the number of health related Web sites that disclose quality standards information. “Quality” here is defined as more than just the quality of information at the site, including among other things, elements that relate to reliability, value and user protections. Outlined below is the information DHHS recommends be disclosed to users on health related Web sites:

- Identity of Web site developers
- Site Owner’s/Developer’s contact information
- Potential conflicts of interest/bias
- Purpose of the site
- Original sources of content
- Privacy and confidentiality protection of personal information
- Site evaluation methodology
- Content updates

A recent article <sup>6</sup>*Proposed Frameworks to Improve the Quality of Health Web Sites* reviews and compares this DHHS framework to three other frameworks for the Quality of HealthSites.(<http://www.medscape.com/GeneralMedicine/journal/2000/v02.n05>)

#### **BOX 5**

#### **EXCERPTS FROM FTC REPORT:**

**Protecting Consumers online: A Federal Trade Commission Report on the First Five Years of Its Internet Law Enforcement Program**

#### **Operation Cure-All:**

**The Commission brought four cases against the marketers of products such as magnetic therapy devices, shark cartilage and CMO. (cetymyristoleate) for their claims that these products could cure a host of serious diseases, including cancer, HIV/AIDS, multiple sclerosis and arthritis. All the companies, which used Web sites to market the products and recruit distributors, entered into settlements with the Commission.**

#### **FTC v.Slim America, Inc.:**

**The defendants were charged with falsely advertising that their weight loss product would produce dramatic weight loss results. After a trial, the Court ordered the defendants to pay \$8.3 million in consumer redress and ordered the individual defendants to post multi-million dollar bonds before engaging in the marketing of weight loss or other products and services.**

#### **FTC v. American Urological Clinic:**

**The defendants touted “Vaegra”, a sham “Viagra” and other impotence treatment products, claiming that the products had been developed by legitimate medical enterprises and proven effective. The Commission obtained an \$18.5 million judgment that requires the defendants to post a \$6 million bond before they promote any impotence treatment in the marketing of impotence treatment or other products and services.**

## **MEDICAL ERRORS**

The Institute of Medicine’s report *To Err is Human: Building a Safer Health System* brought to public attention data known in the medical community for some time<sup>7</sup>. Extrapolating results from a number of studies, the report concluded that 44,000 to 98,000 Americans die each year as a result of medical error. National costs range between \$17 billion and \$29 billion. Of note, is that these data deal almost exclusively with hospitalized patients. The consensus opinion of experts on human error is that many medical errors are the result of systemic problems rather than specific actions by individuals. Complexity of systems has been repeatedly shown to increase the likelihood that errors will occur.

This relationship between complexity and error may have implications for telemedicine practice. As noted in the Institute of Medicine Report, *“Telemedicine: A Guide to Assessing Telecommunications in Health Care”* published in 1996.

*“Telemedicine is not a single technology or a discrete set of related technologies; it is rather, a large and very heterogeneous collection of clinical practices, technologies and organizational arrangements. In addition, widespread adoption of*

<sup>6</sup> Proposed Frameworks to Improve the Quality of Health Web Sites: Review C. Baur, PhD, M.J. Deering, PhD, MedGenMed, Sept. 26, 2000.

<sup>7</sup> Institute of Medicine, *To Err is Human: Building a Safer Health System*, 2000

*effective telemedicine applications depends on a complex, broadly distributed human infrastructure that is only partly in place and is being profoundly affected by rapid changes in health care, information and communications systems.”*

This statement clearly identifies and articulates the rationale for a careful, robust and proactive approach to the identification, reporting and analysis of medical errors encountered in the practice of Telemedicine activities.

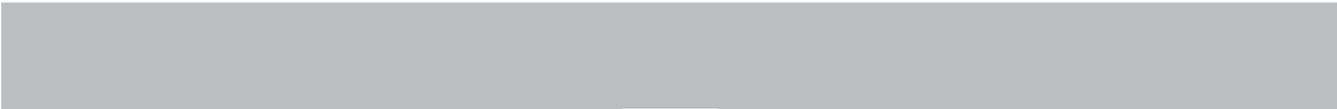
#### NEXT STEPS

- OAT will work with its grantees, the American Telemedicine Association (ATA) and other groups to expand its clinical and technical guidelines.(See <http://telehealth.hrsa.gov/pubs.htm> for current guidelines.)
- OAT will continue to support the work of the Advanced Technology Institute, in developing a Telehealth Deployment Research Testbed. This work is being conducted in conjunction with the Medical University of South Carolina,

West Virginia University Concurrent Engineering Research Center, Arthur D. Little, Oak Ridge National Laboratory, the Low country Healthcare Network and the CPRI-HOST consortium. The testbed will evaluate the effectiveness and practical utility of telehealth technologies by providing both laboratory and “real-world” evaluations.

- OAT will develop a series of measures to be included in its performance measurement data collection system with common data elements to be collected by all OAT grantees. These measures should help document the contribution of telemedicine technologies in reducing the incidence of medical errors.





# Privacy, Security & Confidentiality

## OVERVIEW

Privacy, security and confidentiality concerns are not unique to telemedicine. Industries such as banking, credit card and health care are particularly concerned about personally identifiable information and the possible consequences that could arise should sensitive information be made public. Advances in technology have brought great benefits as well as drawbacks in this area. Many view loss of privacy as part of living in the 21st Century. As Scott McNealy, Chairman and CEO of Sun Microsystems has succinctly put it: “You have no privacy – so get over it!” Fortunately, Congress, a number of state governments and privacy advocates provide a balance to this point of view.

A non-official “working definition”<sup>8</sup> of these concepts is that **Privacy** is an individual’s claim to control the use and disclosure of personal information. This claim is backed by the societal value representing that claim. **Confidentiality** is a status accorded to information that indicates it is sensitive for stated reasons and therefore must be protected and access to it controlled. **Security** are the safeguards (administrative, technical, or physical) in an information system that protect it and its contents against unauthorized disclosure, and limit access to authorized users in accordance with an established policy.

## HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) not only affects employees’ health insurance portability but under the Administrative Simplification (AS) provisions also mandates the development of far reaching national standards for electronic health transactions. These standards include electronic transaction standards for electronic exchange of health

information for administrative purposes; standards for the privacy of individually identifiable health information; a national provider identifier; an employer identifier; and secure electronic signatures, among others.

According to the Act, the Secretary of DHHS must develop final regulations relating to privacy standards by February 2000, if Congress has not acted by August 1999. In 1997, the Secretary together with the National Committee on Vital and Health Statistics (NCVHS), which serves as the statutory public advisory body to the Secretary, sent preliminary recommendations to Congress. In the absence of Congressional action by the mandated deadline, DHHS published a notice of proposed rulemaking in November 1999. Final HIPAA privacy rules were published December 28, 2000 and an DHHS Fact sheet on these rules can be found in Appendix 7. The complete text and the summary can be found at: <http://aspe.hhs.gov/admsimp>.

HIPAA privacy rules cover health plans (e.g., insurers, managed care organizations, federal health programs), health clearinghouses (which unify data in standardized formats) and health care providers, who engage, directly or through contractual arrangements, in HIPAA standard electronic transactions.

Eligible individually identifiable health information can be in electronic, paper or oral format. Thus, the general principles for the use and disclosure of personally identifiable health information are applicable regardless of the form the information is kept in, the methods of transmission, the time sequence of its creation and use, or the way it is communicated.

<sup>8</sup> Willis Ware, Lessons for the Future: Dimensions of Medical Record Keeping, in Health Records: Social Needs and Personal Privacy 43 (Task Force on Privacy, U.S. Department of Health and Human Services (1993)).

Consequently, the proposed standards for the privacy of individually identifiable health information may greatly affect how the healthcare industry as a whole and the telemedicine industry in particular protects privacy in the future.

Potentially one of the most challenging issues for telemedicine practitioners will be HHS' proposal for federal law to preempt state law only when state privacy law is less stringent. If state law is in conflict with federal regulatory requirements, the rules providing more stringent privacy protections should prevail. If many states have more stringent privacy laws, they would all predominate and telemedicine practitioners could be faced with a patchwork of state privacy standards. For example, should telemedicine specialists at a hospital in state A, who confer with patients in states B, C, D and E, determine which state law of the five states is the most stringent for privacy and comply with that state law?

All states have laws governing the use and disclosure of health information; however, there are wide discrepancies in protection, complexity and coverage among them. Moreover, there is typically no one statute governing health data within a state. The Health Privacy Project of the Institute for Health Care Research and Policy at George-town University has compiled a comprehensive 50-state survey of health privacy statutes. A summary of findings is found at the Health Privacy Project Web site at: <http://www.healthprivacy.org/resources/statereports/exsum.html>. At this time, it is too early to predict the impact HIPAA privacy requirements will have on the telehealth industry. On one hand, ensuring and maintaining patient privacy and security measures are good business practice. These practices could provide greater reassurance to those reluctant to participate in telemedicine

for privacy or other reasons. On the other hand, specific requirements that do not reflect telemedicine common practices may create problems. Whether HIPAA requirements prove to be too burdensome for telemedicine practitioners or whether HIPAA will create a "chilling" effect on the industry remains to be seen.

OAT and the Assistant Secretary's Office of Planning and Evaluation have recently funded a study and a conference entitled *Privacy, HIPAA and Telemedicine* that will be completed in Spring 2001. The purpose of the study is to identify privacy issues unique to telemedicine and to determine how HIPAA may affect telemedicine practitioners and patients. The study will draw upon the experience of OAT's grantees, who include over 60 telemedicine networks and over 400 sites.

As we discuss in the Chapter on Emerging Trends and Policy Issues, technology changes in the industry may call for retrofitting HIPAA rules. HIPAA rules do not necessarily cover all consumer-oriented Internet Web sites that collect, store and maintain personally identifiable consumer information. Thus, this privacy measure does not cover an important telemedicine and consumer arena. A further discussion of this subject is highlighted below.

### **CONSUMER PRIVACY AND THE INTERNET**

While a detailed discussion about consumer health privacy online is not within the scope of this report, it is important to note some recent findings. Over the past few years, consumer concerns about privacy on the Internet have escalated. According to a new Gallup poll commissioned by the Medic-Alert Foundation, "almost 90% of participants said that, in general, the confidentiality of their personal health information was important, and almost 85% said they were "concerned" that this information could

be given to others without their consent.”<sup>9</sup> The public’s concern about privacy online may be justified, according to several recent reports and surveys.

For example, Georgetown University recently released a report, called the *Health Privacy Project* (<http://ehealth.chcf.org/>), about the practice of privacy protocols on health related web sites. The five major findings are:

- Consumers are using health Web sites to better manage their health, but their personal information may not be adequately protected.
- Visitors to health Web sites are not anonymous, even if they think they are.
- Health Web sites recognize consumers’ concern about the privacy of their personal health information and have made efforts to establish privacy policies; however, the policies fall short of truly safeguarding consumers.
- There is inconsistency between the privacy policies and the actual practices of health Web sites.
- Health Web sites with privacy policies, that disclaim liability for the actions of third parties on the site, negate those very policies.

Other notable reports that discuss consumer privacy and the Internet include those released by the FTC (see below) and a series of publications, included in a special edition of *Health Affairs*, Vol. 19, No. 6. According to one, entitled *Virtually Exposed: Privacy and E-Health*, “a recent study of

21 leading health related Web sites found that the policies and practices of many fell short of consumers’ expectations for privacy.” The publication also pointed out news stories, highlighting the lax security for information shared and maintained online, as shown in Box 7. Consumers are using health Web sites to better manage their health, but their personal information may not be adequately protected.

#### **BOX 7**

##### **HEALTH RELATED ONLINE SECURITY CONCERNS**

**Global-Healthtrax, which sells health products online, inadvertently revealed names, home phone numbers, bank account and credit care information of thousands of customers on its Web site.**

**Kaiser Permanente mistakenly sent responses to members’ email to the wrong recipients. The email messages, some of which contained sensitive information, affected 858 members who use Kaiser’s on-line services.**

**Finally, thousands of patient records were accidentally made available to the public on the University of Michigan Medical center’s Web**

##### **INDUSTRY SELF REGULATION**

To address these types of problems and concerns, industry has promoted self-regulation by developing standards for Web sites. The Health on the Net Foundation (HON) (<http://www.hon.ch>) and TRUSTe (<http://www.TRUSTe.org>) promote some of the most widely accepted standards and “privacy seals”. Another industry approach is the promotion of “ethical principles.” Two new industry coalitions called the Internet Healthcare Coalition ([ihealthcoalition.org/ethics/ecode.html](http://ihealthcoalition.org/ethics/ecode.html)) and the Health Internet Ethics Coalition ([\[hiethics.org/Principles/index/index.asp\]\(http://www.hiethics.org/Principles/index/index.asp\)\) have proposed the adoption of “ethical principles” or “Ehealth codes” of conduct. Some of the principles recommended by the Internet Healthcare Coalition are candor, honesty, quality and informed consent. Principles adopted by the Health Internet Ethics Coalition include a commitment to adopt a privacy policy, enhanced privacy protection for health related personal information, safeguarding consumer privacy in relationships with third parties, and disclosing ownership and sponsorship information.](http://www.</a></p></div><div data-bbox=)

<sup>9</sup> Source: California Healthcare Foundation, Online News (<http://ehealth.chcf.org>)

## LEGISLATION AND REGULATION

Both the states and Congress have also responded to consumer privacy concerns by introducing a large number of bills that attempt to protect the privacy of personal information collected from the Internet. For example, Congress introduced and passed the Children's Online Privacy Protection Act of 1998. This law requires the FTC to develop regulations, protecting the privacy of personal information collected from and about children on the Internet and to provide greater parental control over the collection and use of that information. Recently, Congress introduced the Health Information Privacy Act (H.R.1941); the Medical Information Protection and Research Enhancement Act of 1999 (H.R.2470); the Consumer Privacy Protection Act (SB 2606 IS); the Consumer Internet Privacy Protection Act of 1999, (H.R.313 IH); and the Consumer Internet Privacy Enhancement Act, among other bills that seek to protect the privacy of consumers who use the Internet.

## THE FEDERAL TRADE COMMISSION'S REGULATORY ROLE

As noted in the previous Chapter, the FDA, Department of Justice and state governments all have roles in online regulation and enforcement but the FTC has emerged as a key online consumer protection regulator, overseeing privacy protection and deceptive trade practices on commercial Web sites. The FTC has published a number of reports on online consumer protection, including *Protecting Consumers Online: A Federal Trade Commission Report on the First Five Years of Its Internet Law Enforcement Program, 1999*. It also recently submitted a Report to Congress, entitled, *Privacy Online: Fair Information Practices in the Electronic Marketplace, May 2000* (<http://www.ftc.gov/os/2000/05/index.htm#22>). Among other things, this Report establishes the FTC's authority to regulate personal data collected online, based on Section 5

of the Federal Trade Commission Act and the Children's Online Privacy Protection Act. However, the FTC still lacks authority to require Web companies to adopt standard information practices such as its Privacy Principles. These four widely accepted information privacy principles are outlined below:

- **Notice:** Provide consumers clear and conspicuous notice of information practices;
- **Choice:** Offer consumers choices as to how their personal identifying information is used;
- **Access:** Give consumers reasonable access to the information the Web site has collected about them;
- **Security:** Take reasonable steps to protect the security of the information collected from consumers.

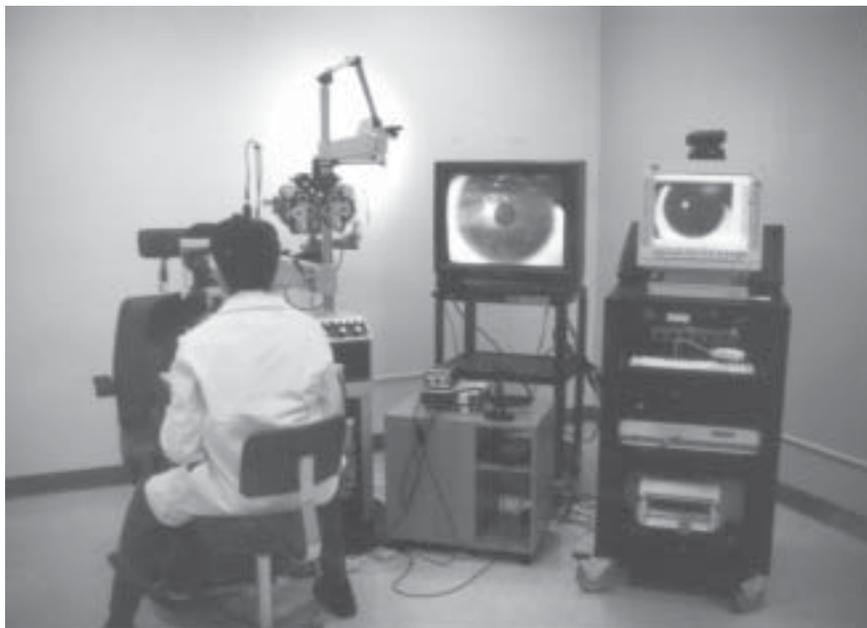
While the FTC continues to strongly encourage industry self-regulation, its 2000 Report Survey demonstrates that self-regulation alone has not been sufficient. According to the Report, only 20% of the busiest Web sites comply with FTC Information Privacy Principles and only about 41% of all Web sites comply with at least two principles.

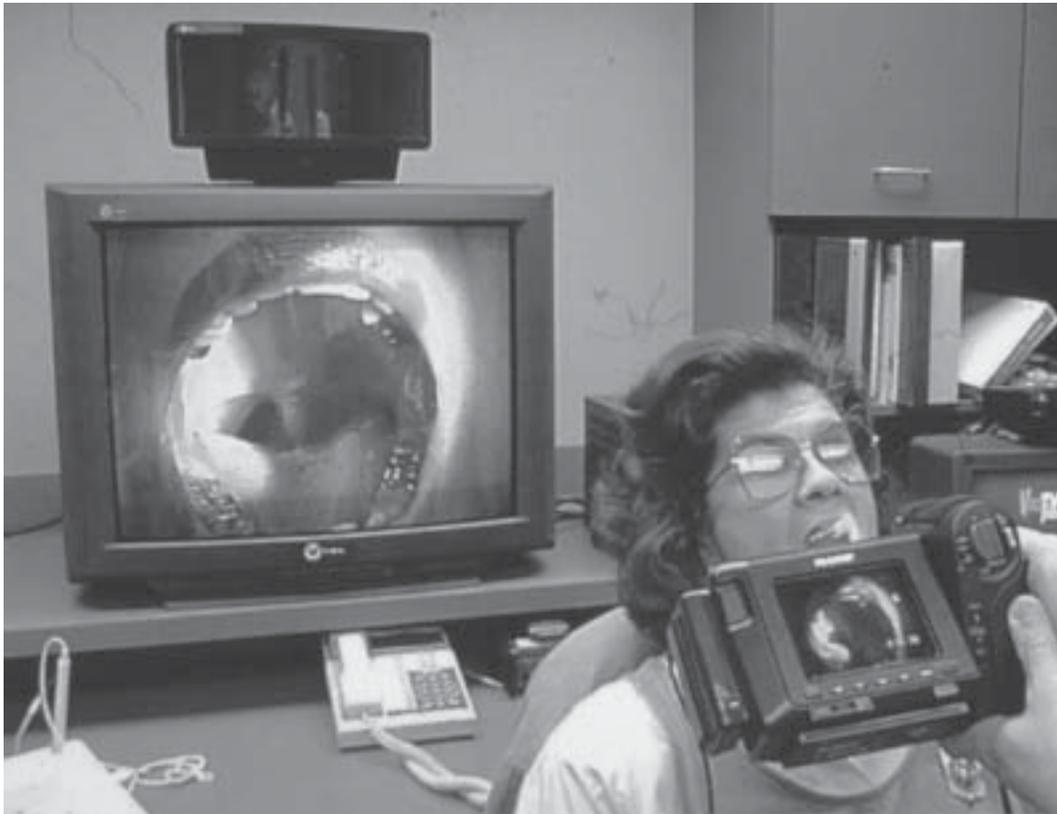
In the past, the FTC has been reluctant to recommend legislative remedies but in the 2000 Report, the FTC offers legislative recommendations to Congress that would set a basic level of privacy protection for all visitors to consumer-oriented commercial Web sites. The legislation would "require all consumer oriented commercial Web sites to the extent already covered by the Children's Online Privacy Protection Act of 1998 (COPPA), to implement the four widely-accepted fair information practice principles, in accordance with more specific regulations to follow."<sup>10</sup>

<sup>10</sup> FTC: Privacy Online: Fair Information Practices in the Electronic Marketplace, A Report to Congress, May 2000, p.38.

## NEXT STEPS

- OAT together with the Office for the Assistant Secretary of Planning and Evaluation have funded a research paper, *Privacy, HIPAA and Telemedicine*, as well as a conference on the same subject. OAT and OASPE anticipate that the final paper and conference will be completed by summer 2001 and the results made available to the public both in print and on OAT's Web site, shortly thereafter.





# Telecommunications Infrastructure

## OVERVIEW

High transmission cost continues to deter telemedicine, particularly in rural areas of the United States. While it may be only a few years away, competition in telecommunications service has not yet reached much of rural America and transmission cost is still a significant part of a rural telemedicine project's overall budget.

Five years ago Congress passed the landmark Telecommunications Act of 1996 (the Act), providing a blueprint for major changes in the telecommunications industry, such as opening up competition between long distance carriers and the Regional Bell Operating Companies. The Act also stated that rural health care providers (HCPs) should have access to advanced telecommunications services at reduced rates.

In the Act, Congress charged the Federal Communications Commission (FCC) with administering the Universal Service program that would provide rural health care providers with a discount on their telecommunication transmission charges equaling the difference between urban and rural transmission rates. In 1997, the FCC established the Universal Service Administrative Company, (USAC) a separate, not for profit entity, which oversees both the E-Rate discount for Schools and Libraries and the Rural Health Care Program (RHCD). After a number of false starts, the Rural Health Care Program issued its first funding commitments on June 25, 1999, five days before the end of the first 18-month program year. In total, 483 rural health care providers received \$3.4 million out of a possible \$400 million, which equaled the total requested support for completed applications received by USAC that year (January 1, 1998 through June 30, 1999).

Since then, the FCC has adopted a number of reforms to the program, as outlined below, which

streamline the discount application process, and address practical concerns voiced by practitioners and others. Specifically, the FCC:

- Expanded the list of telecommunication carriers eligible to participate in the program to include non-ETC (long distance) carriers;
- Streamlined the application process;
- Changed the discount calculation to distance based charges paid by rural healthcare providers rather than a comparison of urban and rural published tariffs; and Eliminated bandwidth and quantity limits so that any bandwidth and any number of services could be supported.

Funding in the second year of program, after reforms were implemented, increased to approximately \$6.1 million. Moreover the FCC and USAC expect that third year funding figures will increase to nearly \$10 million, once all reforms have been in place for a full year. (For a detailed history of the Rural Health Care Division see Appendix 6 and OAT's FCC filing on Universal Service at <http://telehealth.hrsa.gov/pubs.htm>).

## NEXT STEPS

- OAT recently filed comments with the FCC on the question of "possible impediments to deployment and subscribership in unserved and underserved areas of the nation." (See OAT's FCC filing on Pacific Basin at <http://telehealth.hrsa.gov/pubs.htm>) Follow-up with the FCC on this issue continues.
- OAT also filed comments on the FCC's proposal to set aside spectrum for the use of Wireless Medical Telemetry. (See <http://telehealth.hrsa.gov/pubs.htm>) OAT's comments also

reflected concern about adequate spectrum for future telemedicine applications, which may require more bandwidth than currently allocated for telemetry.



# Evaluation and Research

## OVERVIEW

Despite telemedicine's relatively long history, few statistically significant studies of efficacy, patient/physician satisfaction, or effectiveness have been conducted. This dearth of research and data may be due in part to the relatively small number of telemedicine consultations within a given specialty or across specialties within individual telemedicine projects, and to the lack of a standard methodology to study efficacy, patient/physician satisfaction, or effectiveness across projects.

Despite the lack of statistical significance in most of the studies examined by this Report, all showed high patient satisfaction with telemedicine as shown in Table 4. Provider satisfaction was more variable, but generally moderate to high. Moreover, although one cannot generalize to all telemedicine applications, studies of specific services, such as tele-homecare and tele-dermatology, suggest that at least for these services, there may be real cost savings to be realized from telemedicine.

Recent research on evaluation methodologies, such as the Lewin Group Inc.'s draft study on the *Assessment of Approaches to Evaluating Telemedicine*, funded by the Office of the Assistant Secretary for Planning and Evaluation, the Department of Health and Human Services (DHHS), may offer hope for more statistically robust studies in the near future.

## PATIENT AND PHYSICIAN SATISFACTION WITH TELEMEDICINE

To develop a better sense of patient and physician satisfaction, this Report to Congress examined four recent reviews of studies on patient and/or provider satisfaction with telemedicine. These reports offer sufficient breadth or depth in their data to warrant a closer look. Table 4 below highlights the general findings

and the strengths and weaknesses of the reports. They include:

- *Telemedicine for the Medicare Population* by the University of Oregon, funded by the Agency for Healthcare Research and Quality for HHS;
- *Patient Satisfaction with Telemedicine* by the East Carolina University Medical School Telemedicine Center;
- A DRAFT Assessment of *Approaches to Evaluating Telemedicine* by the Lewin Group, Inc, funded by the Office of the Assistant Secretary for Planning and Evaluation; and
- The 1999 Annual Report of the Association of Telehealth Service Providers.

## UNIVERSITY OF OREGON/DHHS REPORT

In 1999, the DHHS' Agency for Healthcare Research and Quality funded the University of Oregon to study *Telemedicine for the Medicare Population*. The Report assesses telemedicine technologies that substitute for face-to-face medical diagnosis and treatment, focusing on three technologies – store and forward, self-monitoring/testing and non-surgical services.

Although the main thrust of the University of Oregon's report is telemedicine technologies and not patient/physician satisfaction with telemedicine, the authors devoted a chapter to their findings on satisfaction.

This chapter drew upon an extensive literature search of both ongoing telemedicine programs around the world and peer reviewed studies assessing the efficacy and cost of telemedicine. The survey of telemedicine literature and projects was extensive and about 30 studies fit the authors' criteria for inclusion in the patient/physician satisfaction chapter. The authors selected 18 studies that examined patient

**Table 4: STUDIES OF PATIENT/PHYSICIAN SATISFACTION WITH TELEMEDICINE**

NAME OF REPORT	NUMBER OF STUDIES REVIEWED	PATIENT SATISFACTION	PROVIDER SATISFACTION	STRENGTHS/WEAKNESS
HHS/University of Oregon (2000)	30 studies	Highly Satisfied	Highly Satisfied	Large survey of studies/ small data samples in each study. Studies only look at one application such as teledermatology.
East Carolina University (2000)	12 studies plus ECU study of 495 teleconsults	Highly Satisfied 98.3% rating for ECU Study	N/A	Large data sample in ECU study with different applications and different settings/small survey of 12 other studies with small data samples.
Association of Telehealth Service	Study based on 132 network responses	N/A	Moderate to Highly Satisfied	Large survey of users/ only looks at technology and users

satisfaction with telemedicine and 10 studies that looked at physician satisfaction. Most of these focused on one clinical specialty such as oncology, psychiatry or dermatology, or on a particular setting such as a prison or emergency room.

The majority of the Report’s selected studies show patients satisfied with their telemedicine treatment. Out of 18 studies examined, only one study showed that most patients preferred face-to-face assessment in lieu of teleconsults. The rest of the studies reveal high levels of satisfaction.

Similarly, the Report found that, overall, physicians’ satisfaction ranges from “satisfied” with telemedicine technical quality to high levels of satisfaction. However, one study out of the ten showed that while the participating psychiatrists were satisfied, given a choice, they preferred face-to-face assessments.

Despite these positive outcomes, the University of Oregon does not draw any conclusions about patient or physician satis-

faction because the authors felt that the studies were not statistically significant. However, the authors do acknowledge that further study or more statistically significant study may not provide any different conclusions than those already offered by these.

As shown in Table 5, most of the studies were based on relatively small data sample sizes ranging from one to about 100 patients. Two of the 18 patient studies were based on larger sample sizes. One was based on a prison inmate population of 576 inmates; the other was based on a sample of 294 dermatological patients. Most of the studies concentrated on only one specialty such as mental health or dermatology. A few studies did assess satisfaction across a few specialties but these were the exception.

TELEMEDICINE CENTER OF THE EAST CAROLINA UNIVERSITY SCHOOL OF MEDICINE

The University of East Carolina (ECU) School of Medicine recently published a report entitled *Patient Satisfaction with Telemedicine*, in the *Telemedicine Journal* (Vol.5, Num.1). In this

report, the authors review other non-telemedicine studies that look at patient satisfaction as well as 12 studies of patient satisfaction in telemedicine applications. They also report their own findings about patient satisfaction based on data collected and evaluated from 495 real-time interactive telemedicine clinical consultations associated with their Telemedicine Center at the School of Medicine. ECU's Telemedicine Center is the hub to eight spoke sites, including six hospitals, one rural health clinic and one maximum-security prison.

ECU's review of 12 telemedicine studies showed patient satisfaction ranging between 71% to 100%. And similar to the University of Oregon's review of 18 telemedicine studies, above, ECU found that the 12 telemedicine studies they reviewed tended to have small sample sizes, ranging from 21 to 292 patients. Also similar to the DHHS studies was the focus on one clinical specialty or a particular setting, such as a prison.

In contrast to the reviewed studies, the ECU study has a much larger data sample size (495 responses) and looks at patient satisfaction across telemedicine specialties. ECU studied a wide variety of clinical specialists including dermatology (33.5%), allergy (21%), cardiology (17%), psychiatry (5.1%), endocrinology (4.2%) and rehabilitation medicine (4.0%).

Patient satisfaction was examined in relation to patient age, gender, race, income and insurance. Overall patient satisfaction with telemedicine applications was found to be a high 98.3%. Patients were highly satisfied with consultations through telemedicine and reported that care was easier to obtain.

ECU suggests several reasons for the high patient satisfaction rate. For example, travel time can be a factor in patient satisfaction. Travel

distances for patients seen over the telemedicine link were on average 81 percent shorter, when compared to the distance to the School of Medicine clinics. The overwhelming majority of patients indicated that telemedicine had made it easier for them to obtain medical care. For example, scheduling a time to see a telemedicine specialist was easier than trying to schedule an appointment with a traditional specialist at ECU's clinics. The amount of time the telemedicine specialist spent on a patient's interview, physical examination and discussion of treatment options was greater and more satisfying to the patient. Part of the reason was that the telemedicine physician received patient information several days prior to the consultation and spent less time gathering information about medical history and more time on the problem at hand.

According to the ECU study, although the telemedicine consult usually takes longer than a traditional exam, "it is plausible that these factors make the patient feel more involved in the consultation and increase(s) satisfaction in the process."

#### ASSOCIATION OF TELEHEALTH SERVICE PROVIDERS

The Association of Telehealth Service Providers' (ATSP) annual report provides findings from a nation wide survey of active telehealth networks. The purpose of the *1999 Report on US Telemedicine Activity*, was to assess the state of telemedicine from the clinical provider's organizational perspective; describe and characterize telemedicine/telehealth activity for 1998 and the first quarter of 1999; and provide reference material. The report does not include patient or physician satisfaction with telemedicine per se but does survey clinical providers'

**BOX 8**  
**ECU STUDY RESULTS**  
**Overall patient satisfaction with telemedicine applications was found to be a high 98.3%. Patients were highly satisfied with consultations through telemedicine, and reported that care was easier to obtain.**

satisfaction with specific types of telemedicine technology. ATSP's 1999 report is based on responses from 132 telehealth networks.

In this report, ATSP's findings on provider satisfaction of telemedicine technology could be viewed as a proxy for health provider satisfaction with telemedicine. The report shows clinical providers' satisfaction with several types of telemedicine technology with data from about 4 to 69 users. Overall the majority (94%) of those interviewed indicated moderate to high levels of satisfaction with the different types of equipment used for telemedicine such as teleradiology, telepathology, videoconferencing, laptops, set tops, home health systems.

Overall, each of these reports and the studies they review or the programs they survey show that patient satisfaction with telemedicine is high and that physician satisfaction is moderate to high. Despite the lack of statistically significant data underpinning most of the studies, it is notable that they all show positive satisfaction.

#### THE OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION/LEWIN GROUP, INC. REPORT

The Office of the Assistant Secretary for Planning and Evaluation (OASPE) of the DHHS funded Lewin Group Inc. has drafted a report titled *Assessment of Approaches to Evaluating Telemedicine*. This draft highlights some of the difficulties of evaluating an industry driven by rapidly changing technology and, given these difficulties, reviews the frameworks needed to appropriately evaluate telemedicine projects. For the report, Lewin conducted a literature search on a number of telemedicine studies and visited five telemedicine sites, first hand. Additionally, 15 telemedicine experts were extensively interviewed. Although the main purpose of the report was assessing telemedicine evaluation and not

patient satisfaction with telemedicine, it does address what subjects should be appraised in the future and what subjects, such as patient satisfaction, may be sufficiently evaluated.

As the Lewin Group Inc.'s Draft Report points out "patient satisfaction with telemedicine has consistently been demonstrated to be high. As such, resources for future evaluations may be better allocated to areas of higher priority."

#### **TELEMEDICINE COST SAVINGS**

Just as there has been an absence of statically significant studies about patient/ provider satisfaction, at present, few telemedicine or other health care projects track the number of patients, who would have been denied access to health care, died or suffered grave consequences in the absence of telemedicine services. As for other tangible benefits related to telemedicine services, they too have not been systematically studied across telemedicine applications on a large scale.

This report briefly looks at several studies that examine telemedicine cost savings for a specific telemedicine application.

Kaiser Permanente Medical Center of Sacramento, California conducted an in-depth study on tele-homecare<sup>11</sup> between 1996 to 1997. (See <http://www.archfammed.com>). In the cost control study home-care patients were assigned to two different groups: a telemedicine intervention group and a control group. The telemedicine intervention group included 102 patients, who had access to a remote video system that allowed nurses and patients to interact in real time; the control group included 110 home health patients, who were visited by nurses. The study showed that remote video technology in the home care setting was effective and well received by patients. Moreover, the quality of care provided by this technology

<sup>11</sup> "Outcomes of the Kaiser Permanente Tele-home Health Research Project Archives of Family Medicine", Volume 9, January 2000.

yielded similar outcomes to those of the control group. Finally, the study found that tele-homecare had the potential for cost savings, which was mostly attributable to hospitalization cost reduction as shown in Box 9.

The University of Tennessee Medical School (UT) also published a study on tele-homecare, conducted between April 1998 and June 1999. UT's *A Case Study of Benefits & Potential Savings in Rural Home Telemedicine*<sup>12</sup> evaluated 444 tele-home health visits to 14 patients using the Home Touch\* system. The Home Touch system included a 13-inch monitor, a speaker phone, a camera and ViaTV converter equipment to provide a real-time home health consultation with UT Home Health nurses in both Knoxville and Jefferson City. The cost of the system was about \$1,500. UT conducted in-depth interviews and monthly surveys with nine of the 14 patients, as well as their caregivers. The results from the Case Study show that:

- 98% of the patients were satisfied with telemedicine;
- 100% said the equipment was easy to use;
- Use of the Home Touch program saved more than 27,000 nurse travel miles between April '98 and June '99, representing potential savings of \$7,091.76 @ \$0.26/mile;
- For the 14 patients seen by telemedicine, the mileage reimbursement and drive time potential savings were \$49.33 per visit.

The Walter Reed Army Medical Center's (WRAMC) Army Telemedicine Directorate recently evaluated the use of teledermatology for several

military sites. Although actual travel and dermatology contract costs for the different military locations were not available, the study found that teledermatology's current benefits are "reduced travel and contract dermatologist costs, increased

Primary Care Manager (PCM) education, increased access to dermatologists and increased patient/provider satisfaction"<sup>13</sup>. This study was based upon findings from WRAMC's Web-Based Telemedicine Consult Management System (TCMS) for teledermatology which conducted 108 clinical consults between April 22, 1998 and July 15 1998.

Finally, the OASPE/ Lewin Group Inc.'s report findings suggest that "some of the commonly recognized types of economic impact of telemedicine applications are costs associated with: patient time and productivity; transportation; capital (equipment, space, etc.); maintenance; and communications; utilization of health care services; and staffing levels and productivity of health professionals."

#### **BOX 9 KAISER TELEHOMECARE STUDY RESULTS**

**The study found no difference in quality indicators, patient satisfaction or use between a control group and a tele-home care group. Although the average direct cost for home health services was \$1,830 in the tele-home group and \$1,167 in the control group, the total mean costs of care, excluding home health care costs, were \$1,948 in the tele-home group and \$2,674 in the control group.**

#### **NEXT STEPS**

- Future evaluations might use the results of the OASPE/Lewin Group Inc. Report to conduct research that yields data with greater statistical significance, by using cross-project evaluation methodologies suggested in the Report.
- Future evaluations should examine

<sup>12</sup> *A Case Study of Benefits & Potential Savings in Rural Home Telemedicine*, Home Healthcare Nurse, vol. 18, No.2, Feb. 2000, p. 125.

\* Home Touch is a registered trademark of the University of Tennessee Medical Center at Knoxville.

<sup>13</sup> *Advanced Concept Technology Demonstrations Letter of Finding*, Telemedicine Directorate, Walter Reed Army Medical Center, 2000.

provider satisfaction, quality and cost implications of telemedicine for specific applications such as tele-homecare, teledermatology and mental health.



# Emerging Trends & Issues

## **OVERVIEW**

Two important trends that may greatly affect the telehealth industry and raise key policy issues are rapid technology changes and the aging population of America. However, predicting the future of the telehealth industry and the technical standards that will underpin “next generation” technology is like predicting the lottery. At most, we can describe some important emerging trends in the telehealth industry over the short term and suggest some related policy issues for the future.

## **TECHNOLOGY CHANGES**

Over the past five years, significant changes in the telehealth industry have been tied to rapid technology advances and the convergence of the communications, media and computer industries. What has been even more dramatic is the exponentially expanding global reach of the Internet, which grew out of a community of U.S. academic and military developers to reach a world wide global audience in just a few years. Technology trends that will likely influence the near future of the telehealth industry and dictate the need for technical standards and guidelines are:

- Next generation Internet;
- The digitization of information; and
- The migration toward wireless communications.

## NEXT GENERATION INTERNET

As consumers and businesses find more ways to use the Internet in their homes and businesses, the next generation Internet will enable these tasks to be accomplished faster, more securely and reliably than on our present system. Part of the anticipated next generation Internet, Internet2 is a joint venture by academia, the federal government and industry. This group is using a new high-speed backbone network with

a core sub-network consisting of a 2.4 Gbps, 13,000-mile research network to test Internet applications such as Internet Protocol (IP) multicasting, differentiated service levels and advanced security. It will also allow researchers to test and resolve problems such as bandwidth constraints, quality and security issues.

## DIGITIZATION

Similar to the next generation Internet, the digital revolution is already upon us. Digitized data, voice, still images and motion-video can be mixed, matched, melded and sent over myriad types of conduits. Advances in digital and compression technology enable vast amounts of information to be stored onto smaller and smaller chips. Applications of this technology include the creation of digital medical libraries and medical databases, as well as the potential to widely adopt Electronic Medical Record Systems and Smart Cards that can hold medical information on a card the size of a credit card. Smart cards are already in use to a limited degree here in the U.S. and more widely overseas. Currently, however, there are no technical standards that can help to easily integrate telemedicine clinical data onto these systems and cards.

## WIRELESS TECHNOLOGY

The use of wireless telemetry in hospital settings is already standard practice as discussed in the Chapter on Safety and Standards. (Examples of medical telemetry equipment include heart, blood pressure and respiration monitors.) In addition, Emergency Medical Services companies are or will be important users of telemetry and other wireless technology. Companies already use wireless telemetry or more advanced wireless technology such as wireless interactive video on emergency vehicles and to communicate with emergency physicians. It enables a paramedic to confer with an

emergency physician for an early assessment, well before the patient's arrival at the hospital. Telemedicine equipment can be as simple as a laptop computer with desktop video conferencing capabilities that provide simultaneous two-way video, two-way voice, vital signs, cardiac and other data to a trauma center. Wireless technology is also useful in an emergency care hospital because emergency physicians, consulting a hand-held wireless device, do not have to leave the patient's side while researching unfamiliar symptoms.

Other wireless technology applications in telemedicine and telehealth will emerge as people adopt wireless applications in their every day lives. For example, the average consumer will be able to carry a mobile library of health information and diagnostics contained in a pocket-sized, handheld wireless computer. With such a wireless palm computer, the practitioner can send patient medical information from the hand held device to another wireless device next door or around the world or to a main data center in the hospital for storage.

## **RELATED TECHNOLOGY POLICY ISSUES**

### POLICY LAGS TECHNOLOGY

Policy makers have not been able to anticipate the changes brought about by the rapid technological advances, revolutionizing the health care industry. In just the past five years, discoveries related to DNA sequencing, the Human Genome Project, cloning and other scientific breakthroughs have raised questions about ethics, privacy and security. These types of discoveries combined with the exponential growth and use of the Internet have created a "policy lag" whereby policy is developed and implemented many months or even years after technology has changed lives, businesses and health care delivery. In the past, the development of regulatory policy, technical standards and protocols could be created over a

number of years but not now. Internet time relates not only to businesses that must adjust to rapid industry changes but also to industry regulators.

### PRIVACY ISSUES

Federal health privacy laws such as the Health Portability and Administrative Act (HIPAA) were conceived a few years before anyone could anticipate the dramatic growth and global reach of the Internet or the convergence of cable, digital, telephony and video technologies. HIPAA rules did not anticipate health practitioners, who could send multiple or a billion copies of a patient record in both text and video clips over the Internet in the form of email. Consequently, HIPAA policy and rules may have to be retrofitted to the current technology landscape and its future possibilities. For example, HIPAA proposed rules do not cover many health-related Web sites. The Next Generation Internet will raise other important privacy and security issues as health care administration and services migrate toward Internet and wireless technologies.

### TECHNICAL STANDARDS AND GUIDELINES

With an increase in the use of advanced wireless technologies, such as hand-held devices with video Internet capabilities, there will be a critical need for technical standards. Standards will help to ensure interoperability, interconnection reliability, quality and security of medical data, images and video transmitted over the airwaves.

Telemedicine providers are already finding it difficult to get their equipment to "talk" to one another even if both perform the same function. Older machines will not talk to newer versions of themselves; different brands will not interconnect. This is frustrating to the health practitioner, trying to provide services, and it is very expensive.

### SPECTRUM FREQUENCY ALLOCATION

As the health care industry adopts more sophisticated technology, requiring more

bandwidth, the bandwidth size, location and status of spectrum frequency that the Federal Communications Commission allocates for medical purposes will likely become a key policy issue for the telehealth industry.

For example, streaming video requires a much larger bandwidth to convey natural movement than bandwidth required for wireless monitoring of vital statistics. An on-going dialogue about the “primary or secondary use” of designated or shared spectrum may be required between the Federal Communications Commission and health related organizations, particularly as the use of telemetry and more advanced wireless telehealth applications is more widely used and moves from institutions to the home or to other health related venues.

Spectrum frequency allocation has also become a growing safety issue. For example, in March 1999, incidences of digital TV interference with wireless medical telemetry equipment occurred at two hospitals in Dallas. (Examples of medical telemetry equipment include heart, blood pressure and respiration monitors.) When new digital TV services were piloted, medical telemetry equipment in these two hospitals did not work. Incidences like these highlight the dangers of electromagnetic interference with the operation of critical medical equipment and underline the need for appropriate spectrum allocation and designation.

In June 2000, the FCC allocated new spectrum and established rules for a Wireless Medical Telemetry Service (WMTS) that allows telemetry equipment to operate on an interference-protected basis. The FCC based its decision on formal comments from a number of organizations including the Food and Drug Administration and the American Hospital Association’s Medical Telemetry Task Force, which provided specific recommendations for spectrum allocation. OAT also filed comments with the FCC, supporting the AHA recommendations and submitted additional

comments concerning the possible future uses and spectrum needs of telemedicine and telehealth applications.

#### BORDER ISSUES

With the Internet, digitization and wireless technologies, the concept of either domestic or international borders will become blurred. As this trend accelerates, cross-state jurisdiction and enforcement issues will become harder to disentangle. Blurring borders may also expand the purview of general practitioners. For instance, if a Physician Assistant or Nurse Practitioner works with a primary care physician or specialist on an ongoing basis and slowly assumes more of the physician’s basic duties, then a gradual change in practice will naturally occur over time. How will states decide to license these practitioners? Will they receive special credentials?

#### **AGING DEMOGRAPHICS, HOME HEALTH CARE AND URBAN TELEMEDICINE**

A discussion of how demographic trends will affect the health industry is not within the scope of this Report but it is hard to ignore the effect the aging of the Baby Boomer generation will have on the health care and telehealth industry. An aging population with a longer life expectancy may mean a larger population of “fragile” elderly, the chronically ill and those requiring rehabilitation.

Given this demographic trend, recent studies and workshops<sup>14</sup> show that home care medical devices were the fastest growing segment of the medical device industry throughout the 1990s. A report from the *Workshop on Home Care Technologies for the 21<sup>st</sup> Century* suggests: “Consumer demand for home health and home health care is not new. When patients have a

<sup>14</sup> “*Future Trends in Medical Device Technology: Results of an Expert Survey*,” FDA, April 1998 and Workshop on Home Care Technologies for the 21st Century, Catholic University, April 1999

choice, and if they have a reasonably stable and caring home environment, they choose to go home, almost without exception. If they have a severe, chronic, difficult condition it is difficult to permit them to go home, unless the home is fitted with the appropriate technology and care giver. We have the opportunity today to make this choice possible by developing technology that is easy to use, suitable for the patients' particular needs and allows access to trained, off-site professionals who can work with the patient on educational/problem areas of concern."<sup>15</sup> Given the movement toward home health care, tele-homecare will most likely play an increasingly larger and more important role in the home health care industry.

Home care in the future may rely on new applications for wireless technology. Tele-homecare can be defined as providing monitoring (telemetry) and home health care services at a distance, using advanced telecommunications and information technology. Aside from videophones, wireless biosensors and feedback loops data can be used to monitor patients who can not get out of bed. OAT grantees have found that tele-home health care has been largely successful, and can allow greater access to care, particularly in rural settings where a nurse may have to travel 200 miles one-way to see a patient at home face-to-face. With tele-homecare, a rural nurse can "visit" six patients in one day, using interactive video instead of traveling 200-300 miles to visit one patient face-to-face for 20

minutes.

Providing tele-home care to the elderly or disabled populations, using telemedicine raises important policy questions about health care access and the reimbursement of telemedicine services for both rural and urban patients.

It can be argued that urban patients who are very elderly, chronically ill, poor or disabled may be as isolated and have as much difficulty getting access to needed health services as those patients, living in rural areas. Most of these urban patients can-not drive to their local clinics and many require assistance getting from point A to point B. Traveling a mile for such an urban patient may be as difficult as the two hundred-mile or more drive, that a mobile rural patient must make to see a specialist.

Reimbursement for both urban and rural patients may be a cost effective policy decision for tele-homecare. Studies show tele-homecare can save money by decreasing unnecessary hospital and emergency room admittances. Around the clock monitoring and nurse availability over videoconferencing has helped patients better self-diagnose and maintain drug therapies.

This policy issue may be resolved at the third party payer level, if cost savings are sufficiently great enough to attract the attention of this group.

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<sup>15</sup> Personal Status Monitoring in the Home, Report Topic B, *Workshop on Home Care Technologies for the 21st Century*, Catholic University, April 1999.

# Conclusion

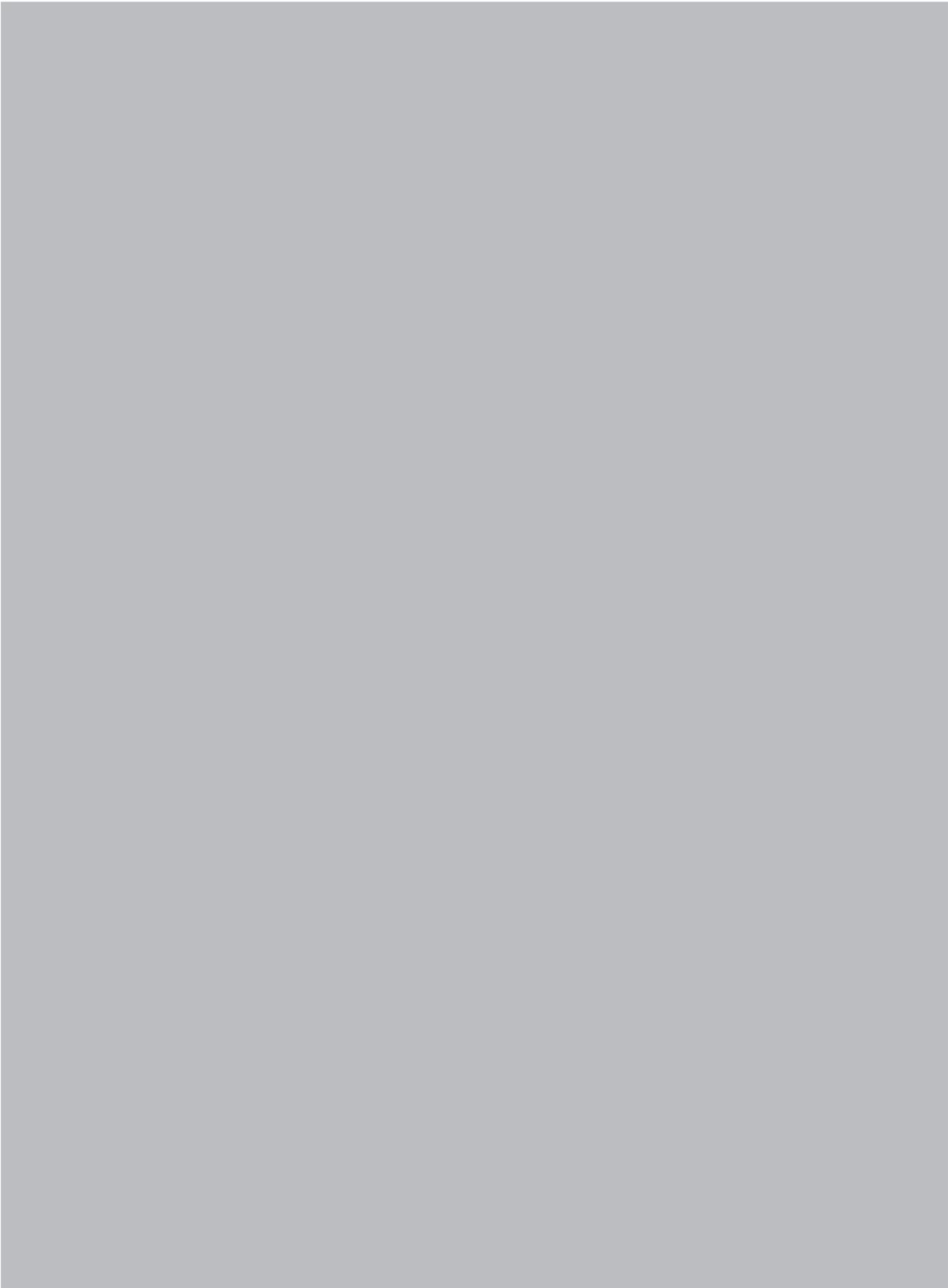
The turn of the century and the millennium is a rare moment in time, a chance to reflect on the past and dream about the possibilities of the future. Just in the last few years there have been medical advances on the scale of DNA sequencing, the Human Genome project and the successful cloning of Dolly the sheep. As the human blueprint is better understood, so can the future health needs of this nation be better addressed. What will a schematic for this future health care system look like? For starters it must provide all Americans - rich or poor, urban or rural, young or old - with access to health care.

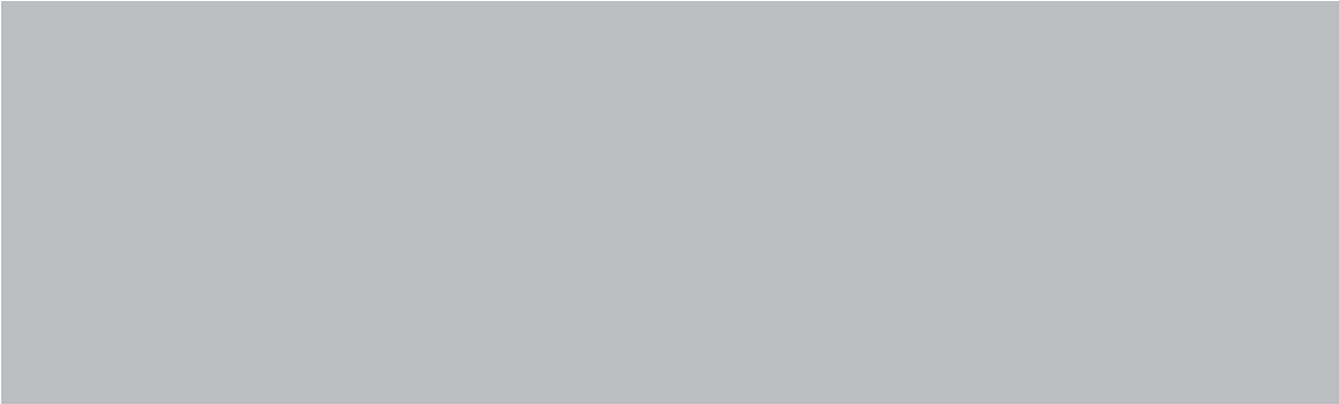
Telemedicine can greatly increase access but it also has the potential to act as a barrier. Much has been written about the “digital divide” separating those, who have access to computers and the Internet, and those who do not. Will there be a similar digital divide for those seeking health care in the future? The argument goes that those without access to the Internet will be left further and further behind in terms of economic welfare and jobs. Does the same logic apply to health information, on-line pharmaceuticals and on-line medical care?

Hence, the Internet provides benefits but also creates concerns. On the one hand, a wealth of health related information is available to consumers at the touch of a fingertip. On the other, use of the Internet for telemedicine raises complex legal, jurisdictional, privacy/security and quality issues. The explosive growth of Internet use for business is bound to change health care delivery and, in turn, to affect how each consumer perceives his/her role in the health care arena. In the future it may be consumers who drive the demand for telemedicine and telehealth rather than health professionals.

The Department of Health and Human Services continues to address both the traditional challenges to the development of telehealth, such as reimbursement, and to monitor new trends in the industry. Working with Congress, the Department strives to increase health care access for America’s most underserved populations through telemedicine.







## Appendix 1

# THE MEDICARE, MEDICAID AND SCHIP BENEFITS IMPROVEMENT AND BENEFICIARY PROTECTION ACT OF 2000 SECTIONS 223 AND 504 AND A COMPARISON OF LEGISLATION BILLS RELATING TO TELEMEDICINE REIMBURSEMENT

**SIDE BY SIDE COMPARISON OF HOUSE AND SENATE BILLS RELATING  
TO TELEMEDICINE PROVISIONS**

**CENTER FOR TELEMEDICINE LAW**  
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Email: telemedlaw@ctl.org

S. 2505	H.R. 5291	WAYS AND MEANS	HR 4577
<p><b>Title:</b> Telehealth Improvement and Modernization Act of 2000</p>	<p><b>Title:</b> Revision of Medicare Reimbursement for Telehealth Services</p>	<p><b>Title:</b> Section 324: Expansion of Medicare Payment for Telehealth Services</p>	<p><b>Title:</b> Revision of Medicare Reimbursement for Telehealth Services</p>
<p><b>Reimbursement:</b> Secretary shall pay to a physician or practitioner at a distant site that provides an item or service the amount equal to that if it had been provided without telehealth.</p>	<p><b>Reimbursement:</b> Not later than April 1, 2001 HHS shall pay for telemedicine services that would be made under part B, Title XVIII of SSA.</p>	<p><b>Reimbursement:</b> Same as Senate.</p>	<p><b>Reimbursement:</b> Secretary shall pay to a physician or practitioner at a distant site that furnishes a telehealth service to an eligible telehealth individual and amount equal to that if it had been provided without use of a telecommunications system.</p>
<p><b>Facility Fee:</b> An amount equal to: 1) for 2000 and 2001, \$20; and 2) for a subsequent year, the facility fee will be increased by the percentage increase in the MEI</p>	<p><b>Facility Fee:</b> Same as Senate except facility fee begins April 1, 2001 and runs through 2002 at \$20.</p>	<p><b>Facility Fee:</b> Same as Senate except facility fee for July 1, 2001 through December 2001 and for 2002 is \$20. Balanced billing explicitly prohibited.</p>	<p><b>Facility Fee:</b> An amount equal to: 1) for 7/1/01 through 2002, \$20; and 2) for a subsequent year, the facility fee will be the same as 1) or increased by the percentage increase in the MEI</p>

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<p><b>Sites Eligible for Facility Fee:</b></p> <p><u>Tier 1.</u> On or before January 1, 2002: 1) the office of a physician or practitioner. 2) a critical access hospital; 3) a rural health clinic; and 4) a Federally qualified health center.</p> <p><u>Tier 2.</u> On or before January 1, 2003: 1) a hospital; 2) a skilled nursing facility; 3) a comprehensive outpatient rehabilitation facility; 4) an ambulatory surgical center; 5) an Indian Health Service facility; and 6) a community mental health center.</p>	<p><b>Sites Eligible for Facility Fee:</b></p> <p><u>Tier 1</u> Same sites as Senate except coverage begins on or after April 1, 2001.</p> <p><u>Tier 2</u> On or before January 1, 2002: 1) a hospital; 2) a skilled nursing facility; 3) a comprehensive outpatient rehabilitation facility; 4) a renal dialysis facility; 5) an ambulatory surgical center; 6) a hospital or skilled nursing facility of the Indian Health Services; and 7) a community mental health center</p>	<p><b>Sites Eligible for Facility Fee:</b></p> <p>Includes only those sites listed below and only if the site is located in a HPSA that is located in all or part of a rural area: 1) The office of a physician or practitioner; 2) A rural health clinic; 3) A Federally Qualified Health Center; and 4) A critical access hospital</p>	<p><b>Sites Eligible for Facility Fee:</b></p> <p><b>Originating Site:</b> 1) An area designated as a rural health professional shortage area 2) In a county that is not in a MSA 3) A Federal telemedicine demonstration project.</p> <p><b>Sites:</b> 1) The office of a physician or practitioner; 2) A critical access hospital; 3) A rural health clinic; 4) A Federally Qualified Health Center; and 5) A hospital</p>
<p><b>Telepresenter:</b> Telepresenter not required</p>	<p><b>Telepresenter:</b> Same as Senate except, "unless it is medically necessary as determined by the physician or practitioner at the distant site"</p>	<p><b>Telepresenter:</b> Except for certain psychiatric services, an individual shall be presented by a physician or practitioner or an RN.</p>	<p><b>Telepresenter:</b> Telepresenter not required, unless it is medically necessary (as determined by the physician or practitioner at the distant site).</p>

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<p><b>Geographical Areas Covered:</b></p> <p>Applies to eligible Telehealth Beneficiaries residing in:</p> <ol style="list-style-type: none"> <li>1) a HPSA,</li> <li>2) a county not included in a Metropolitan Statistical Area; and</li> <li>3) an inner-city area that is medically underserved.</li> </ol> <p><b>Codes Covered:</b></p> <p>Payment will be made for professional consultations, office visits, office psychiatry services, including any service identified as of July 1, 2000, by HCPCS codes 99241-99275, 99201-99215, 90804-90815, and 90862, and any additional item or service specified by the Secretary</p> <p><b>Additionally:</b> Directs Secretary to identify appropriately covered services and to report back 2 years within enactment of the legislation.</p>	<p><b>Geographical Areas Covered:</b></p> <p>Same as the Senate except: An inner city that is considered medically underserved effective January 1, 2002, and a facility which participates in a Federal telemedicine demonstration project.</p> <p><b>Codes Covered:</b></p> <p>Same as Senate except for coding: Codes covered include 99241-99275, 99201-99215, 90804-90809 and 90862.</p> <p><b>Additionally:</b> Directs Secretary to identify appropriately covered services and to report back within 2 years of enactment of the legislation.</p>	<p><b>Geographical Areas Covered:</b></p> <p>Same as Sites Eligible for Facility Fee. Only if the site is located in a HPSA that is located in all or part of a rural area:</p> <ol style="list-style-type: none"> <li>1) The office of a physician or practitioner;</li> <li>2) A rural health clinic;</li> <li>3) A Federally Qualified Health Center; and</li> <li>4) A critical access hospital</li> </ol> <p><b>Codes Covered:</b></p> <p>Same as Senate, except for coding: Codes covered include 99241-99275, 99201-99215, 90804-90809 and 90862.</p> <p><b>Also, directs the Comptroller General to conduct a study similar to that called for in Senate bill and requires a report in 3 years.</b></p>	<p><b>Geographical Areas Covered:</b></p> <p>Originating Sites including:</p> <ol style="list-style-type: none"> <li>1) An area designated as a rural health professional shortage area</li> <li>2) In a county that is not in a MSA</li> <li>3) A Federal telemedicine demonstration project.</li> </ol> <p><b>Codes Covered:</b></p> <p>telehealth service means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241-99275, 99201-99215, 90804-90809, and 90862, and as subsequently modified by the Secretary</p> <p><b>Additionally,</b> requires the Secretary to establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes) as appropriate</p>

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<p><b>Eligible Telehealth Providers:</b></p> <p>Expands upon physician only provision in BBA by adding: 1) a practitioner described in section 1842(b)(18)(C) of the Social Security Act; and 2) physical, occupational or speech therapist.</p>	<p><b>Eligible Telehealth Providers:</b></p> <p>Same as Senate except it does not include physical, occupational or speech therapists</p>	<p><b>Eligible Telehealth Providers:</b></p> <p>Refers to physicians and practitioners but does not define them.</p>	<p><b>Eligible Telehealth Providers:</b></p> <p>A physician, (as defined in section 1861 (r) or a practitioner as described in section 1824 (b)(18)(C)</p>
<p><b>Home Health:</b></p> <p>Nothing in this section or in section 1895 of the Social Security Act (42 U.S.C. 1395fff) shall be construed as preventing a home health agency furnishing a home health unit of service for which payment is made under the prospective payment system established in such section for such units of service from furnishing the service via a telecommunications system.</p> <p><b>LIMITATION-</b> Nothing in this section shall require the Secretary to consider a home health service provided in the manner described in paragraph (1) to be a home health visit for purposes of--</p> <p>(A) determining the amount of payment to be made under such prospective payment system; or</p> <p>(B) any requirement relating to the certification of a physician required under section 1814(a)(2)(C) of such Act (42 U.S.C. 1395f(a)(2)(C)).</p>	<p><b>Home Health:</b></p> <p>Same as the Senate, except the language "via a telecommunication system" is excluded.</p>	<p><b>Home Health:</b></p> <p>Section 504 states:</p> <p>Nothing in this section shall be construed as preventing a home health agency furnishing a home health unit of service for which payment is made under the PPS established by this section for such units of service from furnishing services via a telecommunication system if such services:</p> <ol style="list-style-type: none"> <li>1. Do not substitute for home health services ordered as part of a plan of care certified by a physician; and</li> <li>2. Are not considered to be a home health visit for purposes of eligibility or payment under this title.</li> </ol>	<p><b>Home Health: Section 504</b></p> <p>Nothing in this section shall be construed as preventing a home health agency furnishing a home health unit of service for which payment is made under the prospective payment system established by this section for such units of service from furnishing services via a telecommunications system if such services -</p> <p>(A) do not substitute for in-person home health services ordered as part of a plan of care certified by a physician; and</p> <p>(B) are not considered a home health visit for purposes of eligibility or payment under this title.</p>

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<p><b>Store and Forward:</b></p> <p>Re: Section 4206(a)(1) of the BBA, in the case of any Federal telemedicine demonstration program in Alaska or Hawaii, the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in a single or multimedia format(s).</p>	<p><b>Store and Forward:</b></p> <p>Same as Senate</p>	<p><b>Store and Forward:</b></p> <p>No provision.</p>	<p><b>Store and Forward:</b></p> <p>In the case of any Federal telemedicine demonstration program conducted in in Alaska or Hawaii, the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.</p>
<p><b>Fee Sharing and Payment of Presenter:</b></p> <p>Fee sharing provisions in BBA '97 are eliminated.</p>	<p><b>Fee Sharing and Payment of Presenter:</b></p> <p>Same as Senate</p>	<p><b>Fee Sharing and Payment of Presenter:</b></p> <p>Nothing prohibits the physician or practitioner from sharing a portion of the fee that he or she receives from Medicare for an eligible telehealth service with a physician or practitioner who serves as a telepresenter at the originating site;</p> <p>Payment for an RN who serves as a telepresenter shall be made by the distant site physician or practitioner or the originating site facility that is the RN's employer;</p> <p>The provisions of section 1877 shall apply to payments that a physician or practitioner at a distant site makes to a referring physician or practitioner who does not serve as a telepresenter at the originating site.</p>	<p><b>Fee Sharing and Payment of Presenter:</b></p> <p>Fee sharing provisions in BBA '97 are eliminated.</p>

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## H.R.5661

### Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Introduced in the House)

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#### SEC. 223. REVISION OF MEDICARE REIMBURSEMENT FOR TELEHEALTH SERVICES.

(a) TIME LIMIT FOR BBA PROVISION- Section 4206(a) of BBA (42 U.S.C. 1395l note) is amended by striking 'Not later than January 1, 1999' and inserting 'For services furnished on and after January 1, 1999, and before October 1, 2001'.

(b) EXPANSION OF MEDICARE PAYMENT FOR TELEHEALTH SERVICES- Section 1834 (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

(m) PAYMENT FOR TELEHEALTH SERVICES-

(1) IN GENERAL- The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r)) or a practitioner (described in section 1842(b)(18)(C)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term 'telecommunications system' includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) PAYMENT AMOUNT-

(A) DISTANT SITE- The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.

(B) FACILITY FEE FOR ORIGINATING SITE- With respect to a telehealth service, subject to section 1833(a)(1)(U), there shall be paid to the originating site a facility fee equal to--

(i) for the period beginning on October 1, 2001, and ending on December 31,

2001, and for 2002, \$20; and

`(ii) for a subsequent year, the facility fee specified in clause (i) or this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

`(C) TELEPRESENTER NOT REQUIRED- Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

`(3) LIMITATION ON BENEFICIARY CHARGES-

`(A) PHYSICIAN AND PRACTITIONER- The provisions of section 1848(g) and subparagraphs (A) and (B) of section 1842(b)(18) shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

`(B) ORIGINATING SITE- The provisions of section 1842(b)(18) shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

`(4) DEFINITIONS- For purposes of this subsection:

`(A) DISTANT SITE- The term `distant site' means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

`(B) ELIGIBLE TELEHEALTH INDIVIDUAL- The term `eligible telehealth individual' means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

`(C) ORIGINATING SITE-

`(i) IN GENERAL- The term `originating site' means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located--

`(I) in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));

`(II) in a county that is not included in a Metropolitan Statistical Area; or

`(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

`(ii) SITES DESCRIBED- The sites referred to in clause (i) are the following sites:

`(I) The office of a physician or practitioner.

`(II) A critical access hospital (as defined in section 1861(mm)(1)).

`(III) A rural health clinic (as defined in section 1861(aa)(s)).

`(IV) A Federally qualified health center (as defined in section 1861(aa)(4)).

`(V) A hospital (as defined in section 1861(e)).

`(D) PHYSICIAN- The term `physician' has the meaning given that term in section 1861(r).

`(E) PRACTITIONER- The term `practitioner' has the meaning given that term in section 1842(b)(18)(C).

`(F) TELEHEALTH SERVICE-

`(i) IN GENERAL- The term `telehealth service' means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241-99275, 99201-99215, 90804-90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

`(ii) YEARLY UPDATE- The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).'

(c) CONFORMING AMENDMENT- Section 1833(a)(1) (42 U.S.C. 1395l(1)), as amended by section 105(c), is further amended--

(1) by striking `and (T)' and inserting `(T)'; and

(2) by inserting before the semicolon at the end the following: `, and (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section'.

(d) STUDY AND REPORT ON ADDITIONAL COVERAGE-

(1) STUDY- The Secretary of Health and Human Services shall conduct a study to identify--

(A) settings and sites for the provision of telehealth services that are in addition to those permitted under section 1834(m) of the Social Security Act, as added by subsection (b);

(B) practitioners that may be reimbursed under such section for furnishing telehealth services that are in addition to the practitioners that may be reimbursed for such services under such section; and

(C) geographic areas in which telehealth services may be reimbursed that are in addition to the geographic areas where such services may be reimbursed under such section.

(2) REPORT- Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations for legislation that the Secretary determines are appropriate.

(e) EFFECTIVE DATE- The amendments made by subsections (b) and (c) shall be effective for services furnished on or after October 1, 2001.

#### **SEC. 224. EXPANDING ACCESS TO RURAL HEALTH CLINICS.**

(a) IN GENERAL- The matter in section 1833(f) (42 U.S.C. 1395l(f)) preceding paragraph (1) is amended by striking 'rural hospitals' and inserting 'hospitals'.

(b) EFFECTIVE DATE- The amendment made by subsection (a) shall apply to services furnished on or after July 1, 2001.

#### **SEC. 225. MEDPAC STUDY ON LOW-VOLUME, ISOLATED RURAL HEALTH CARE PROVIDERS.**

(a) STUDY- The Medicare Payment Advisory Commission shall conduct a study on the effect of low patient and procedure volume on the financial status of low-volume, isolated rural health care providers participating in the medicare program under title XVIII of the Social Security Act.

(b) REPORT- Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under subsection (a) indicating--

(1) whether low-volume, isolated rural health care providers are having, or may have, significantly decreased medicare margins or other financial difficulties resulting from any of the payment methodologies described in subsection (c);

(2) whether the status as a low-volume, isolated rural health care provider should be designated under the medicare program and any criteria that should be used to qualify for such a status; and

(3) any changes in the payment methodologies described in subsection (c) that are necessary to provide appropriate reimbursement under the medicare program to low-volume, isolated rural health care providers (as designated pursuant to paragraph (2)).

(c) PAYMENT METHODOLOGIES DESCRIBED- The payment methodologies described in this subsection are the following:

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## H.R.5661

**Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Introduced in the House)**

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### **SEC. 504. USE OF TELEHEALTH IN DELIVERY OF HOME HEALTH SERVICES.**

Section 1895 (42 U.S.C. 1395fff) is amended by adding at the end the following new subsection:

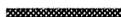
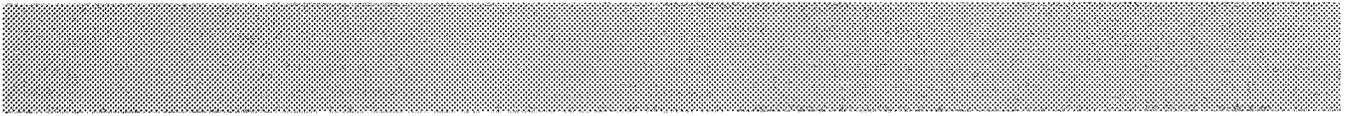
**`(e) CONSTRUCTION RELATED TO HOME HEALTH SERVICES-**

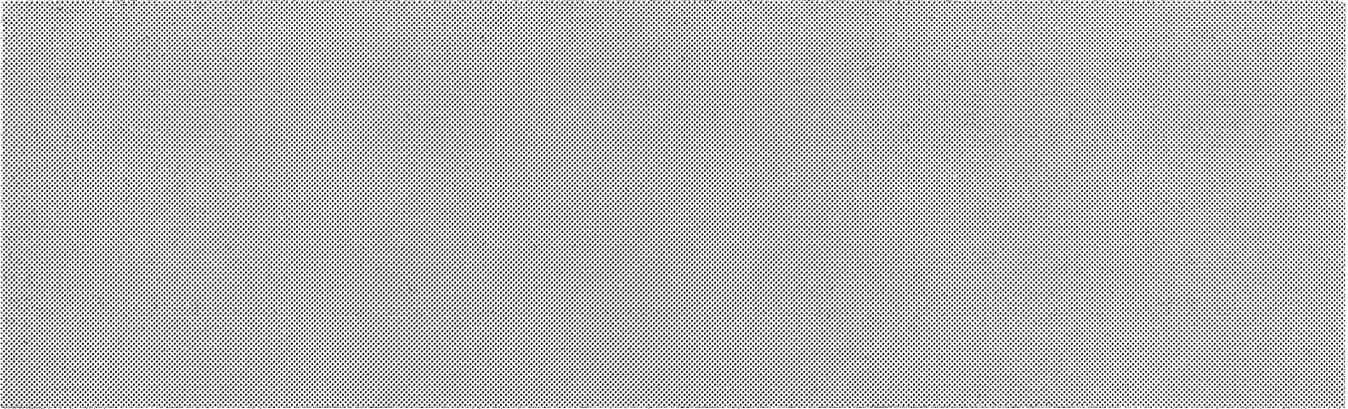
**`(1) TELECOMMUNICATIONS-** Nothing in this section shall be construed as preventing a home health agency furnishing a home health unit of service for which payment is made under the prospective payment system established by this section for such units of service from furnishing services via a telecommunication system if such services--

**`(A)** do not substitute for in-person home health services ordered as part of a plan of care certified by a physician pursuant to section 1814(a)(2)(C) or 1835(a)(2)(A); and

**`(B)** are not considered a home health visit for purposes of eligibility or payment under this title.

**`(2) PHYSICIAN CERTIFICATION-** Nothing in this section shall be construed as waiving the requirement for a physician certification under section 1814(a)(2)(C) or 1835(a)(2)(A) of such Act (42 U.S.C. 1395f(a)(2)(C), 1395n(a)(2)(A)) for the payment for home health services, whether or not furnished via a telecommunications system.'





## **Appendix 2**

# **Telemedicine Related State Licensure Laws**

**Alabama Code §§ 34-24-502,503,507 (1997).**

Special licensure for out-of-state physicians

**Ark. Code Ann. § 17-95-206 (1997). Arkansas Session Law 220 (1999)**

Full licensure for out-of-state physicians (1997)

Nurse Licensure Compact (1999)

**California Business and Professional Code §§ 2060,2290.5,2052.5 (1997).**

Registration program for telemedicine providers created by Board of Medicine

**Colorado Rev. Statute Ann § 12-36-106 (1998). SB 19 62<sup>nd</sup> Legislature (1999)**

Full licensure for out-of state physician

Limited license for physicians affiliated with Shriners Hospital for Children (1999)

**Connecticut General Statute § 20-9 (1997).**

Full licensure for out-of-state physicians

**Delaware HB 439 (1999)**

Interstate Nurse Licensure Compact (2000)

**Georgia Code Ann. § 43-34-31.1 (1998).**

Full licensure for out-of-state physicians

**Hawaii Rev. Statute § 453-2 (1997). SB 1136 (1999)**

Permits out-of-state physicians without in-state offices to practice telemedicine

State licensure not required if out-of-state physician is providing consultation to an in-state licensed physician (1999)

**225 Illinois Comp. Statute 60-49.5 (West 1998).**

Full licensure for telemedicine practitioner

**Indiana Code Ann. § 25-22.5-1-1.1 (Michie1998).**

Full licensure to practice telemedicine

**Iowa HF 2105 (3/2000)**

Interstate Nurse Licensure Compact

**Kansas Administrative Regulations § 100-26-1 (1996).**

Full licensure for out-of-state physicians

**Maine ME LD 2558 (2000).**

Interstate Nurse Licensure Compact

**Maryland SB 490 (1999)**

Interstate Nurse Licensure Compact

**Mississippi Code Ann. § 73-25-34 (1997). MS HB 535 (2000)**

Full licensure for out-of state physicians practicing telemedicine

Interstate Nurse Licensure Compact

**Montana HB 399, 56<sup>th</sup> Legislature (1999)**

Telemedicine certificate issued by Board of Medical Examiners.

**Nebraska Rev. Statute § 71-1,102 (1998). NE L.B. 523 (1999).**

Full licensure for out-of-state physicians

Interstate Nurse Licensure Compact effective 7/1/2000

**Nevada Rev. Stat. Ann. § 630-020- (Michie 1997). Nev. Rev. Stat. Ann. tit. 54 ' 630.020 (2000).**

Full licensure for out-of-state physicians practicing telemedicine  
Exemption for physicians called into the state by a licensed in-state physician for a consultation on an irregular basis.

**New Hampshire SB 53 (1999)**

Full licensure for out-of-state physicians providing contractual or frequent teleradiology service to NH patients.

**North Carolina General Statute § 90-18 (1997). N.C. Sess. Law 1999-0245 '90-171.80 - 171.93 (1999)**

Full licensure for out-of-state physicians.  
Interstate Nurse Licensure Compact (effective 7/1/2000)

**North Dakota HB 1158 (1999)**

Full licensure required unless out-of-state physician is in consultation with in-state licensed physician physically located in ND and primarily responsible for the care of patient.

**Oklahoma Statute title 36, § 6802(1997)**

Full licensure for out-of-state physicians

**Oregon SB 600 (1999)**

Special purpose telemedicine license for out-of-state physicians. Allows consultations and emergency care without license.

**South Dakota Codified Laws § 36-4-41- (Michie 1998) SD H.B. 1045 (2000).**

Full licensure for out-of-state physicians, using electronic means to treat persons located in SD. Interstate Nurse Licensure Compact, effective 1/1/2001.

**Tennessee Code Ann. § 63-6-201 (1998), Tenn. Comp.R.& Regulations Chap 0880-21.16 (1998)**

Special purpose license for out-of-state physicians.

**Texas Rev. Civ. Stat. Art. 4495b, §3.06 (I) (1998), 22 Tex. Admin. Code §§ 174.1-174.15 / HB 1342, 76<sup>th</sup> Legislature (1999)**

Special purpose license for telemedicine practitioners (1998)  
Interstate Nurse Licensure Compact, enacted 6/19/99

**Utah Code Ann. § 58-31b-102 (1998), Utah Code Ann § 58-1-307 (1998), SB 26 (1999)**

Full licensure for out-of-state physicians  
Interstate Nurse licensure compact, effective 1/1/2000

**West Virginia HB 2082, 74<sup>th</sup> Legislature, (1999)**

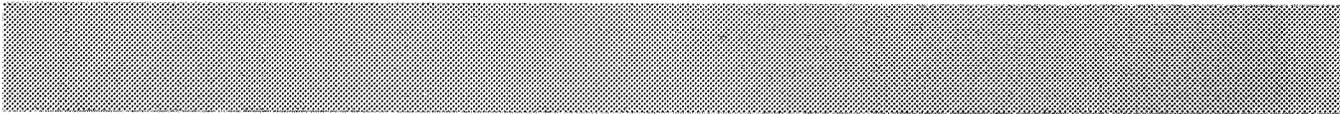
State licensure for the practice of telemedicine with some consultation exceptions.

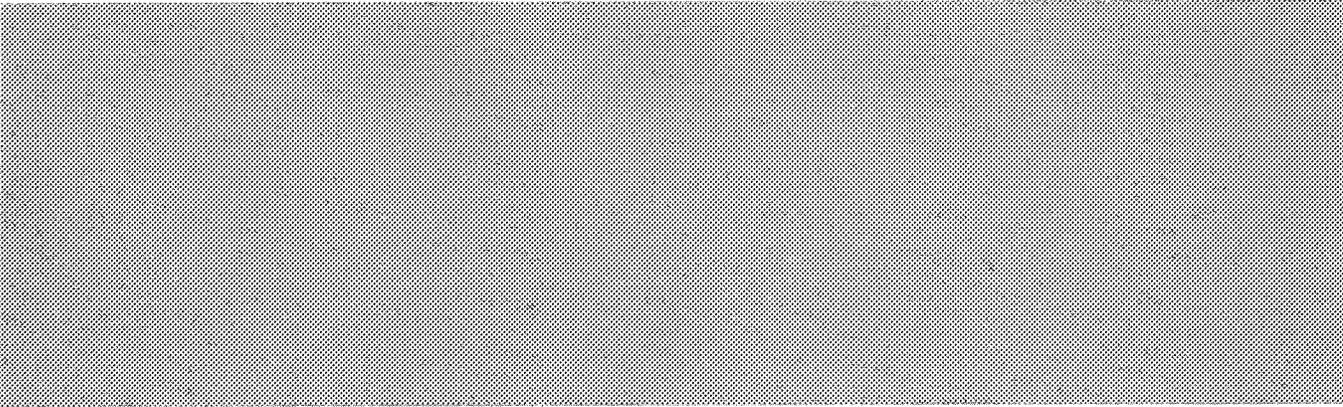
**Washington WI A.B. 305 (1999).**

Interstate Nurses Licensure Compact effective 1/1/2000

**Wyoming Rules 024-052-001 § 4(d) (1998)**

Full licensure for out-of-state physicians





## Appendix 3

**Letter from the  
National Association of  
Pediatric Nurses Associates  
and Practitioners, Inc.  
and Association of  
Women's Health,  
Obstetric and  
Neonatal Nurses**

National Association of Pediatric  
Nurse Associates & Practitioners, Inc.  
1101 Kings Highway, North  
Suite 206  
Cherry Hill, NJ 08034-1912

*Association of Women's Health,  
Obstetric and Neonatal Nurses*  
2000 L Street, N.W.  
Washington, D.C. 20036

January 19, 2000

SENT VIA FAX - 301.443.1330

Ms. Joanne Kumekawa  
Director, Telehealth Policy Development  
Office for the Advancement of Telehealth  
Health Resources and Services Administration  
U.S. Department of Health and Human Services  
5600 Fishers Lane, Room 11A55  
Rockville, MD 20857

Dear Ms. Kumekawa:

On behalf of the more than 5,600 members of the National Association of Pediatric Nurse Associates and Practitioners (NAPNAP) and the more than 22,000 members of the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), we appreciate the opportunity to provide comments for the update of the Office for the Advancement of Telehealth web site.

*Comments from NAPNAP and AWHONN:*

The National Council of State Boards of Nursing (NCSBN) Multistate Licensure Compact Proposal, while well intentioned, falls far short of its stated goals and would be harmful to the nursing profession. The proposal contains numerous problems and creates serious safety concerns with the application of the compact and its effect on patient confidence with the nursing profession.

- Despite the claims to the contrary by the NCSBN, the Multistate Licensure Compact Proposal creates the effect of the lowest common denominator as it pertains to licensure standards. Nurses from states with lower standards are not required to meet the more stringent standards from other compact states.

- There is nothing in the compact language that would require a nurse to disclose the state where they are licensed to a patient or anyone else when practicing in another state. At the request of the NCSBN, the Wisconsin State Senate rejected a proposed amendment which would have required a nurse to register with the licensing board before practicing in Wisconsin. Currently, compact states do not know who is practicing in their state on any given day.
- The compact also raises questions about the use of foreign nurses. The Texas compact language allows nurses from Mexico to enjoy the same practice privileges as Texas nurses.

The same is true for Canadian nurses in the Wisconsin compact language. Canadian and Mexican nurses are not required to meet the education, certification, and licensure standards as their American counterparts. This has created a double standard and potentially puts United States citizens at risk by utilizing less qualified nursing personnel.

- The proposed Coordinated Licensure Information System (CLIS) would include actions against nurses not only by licensing boards, but also courts and other regulatory bodies, which could include traffic violations, tax issues, and family disputes. This system does not ensure protections or safeguards which are included in the new federal Healthcare Integrity and Protection Data Bank (HIPDB). There are no confidentiality protections for nurses, or limits on the kinds of data collected on nurses, despite the claims from the NCSBN that protections will be in place. In fact, the NCSBN and the individual State Boards of Nursing have opposed proposals which would create limits and protections. This confidential and private data will be in the hands of a private third party without accountability provisions to any group (local, state or federal), or individual nurse.

The CLIS would also be the third data bank for nurses. Already in place are the National Practitioner Data Bank (NPDB) and the HIPDB. This third data bank is an unnecessary duplication of efforts which will add costs without creating greater safety or efficiency for those responsible for ensuring the delivery of quality health care.

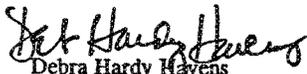
- Individual state's rights and constitutionality questions continue to be raised. The Attorneys General in Kansas and Nebraska have ruled that the Multistate Licensure Compact Proposal violates their respective state constitution. The Kansas Attorney General writes, "Because the compact would, through absolute reciprocity, allow other states' legislatures the unqualified right to determine the qualifications for the practice of nursing in this state by nonresidents, we believe the compact would be an unconstitutional delegation of legislative authority."

The NCSBN has chosen to ignore, rather than attempt to address, the problems outlined by the Attorneys General. This is also particularly disappointing, as we believe that even if the compact is successful, it will simply be a matter of time before it is challenged in court, which will ultimately be paid by nurses through licensure fees.

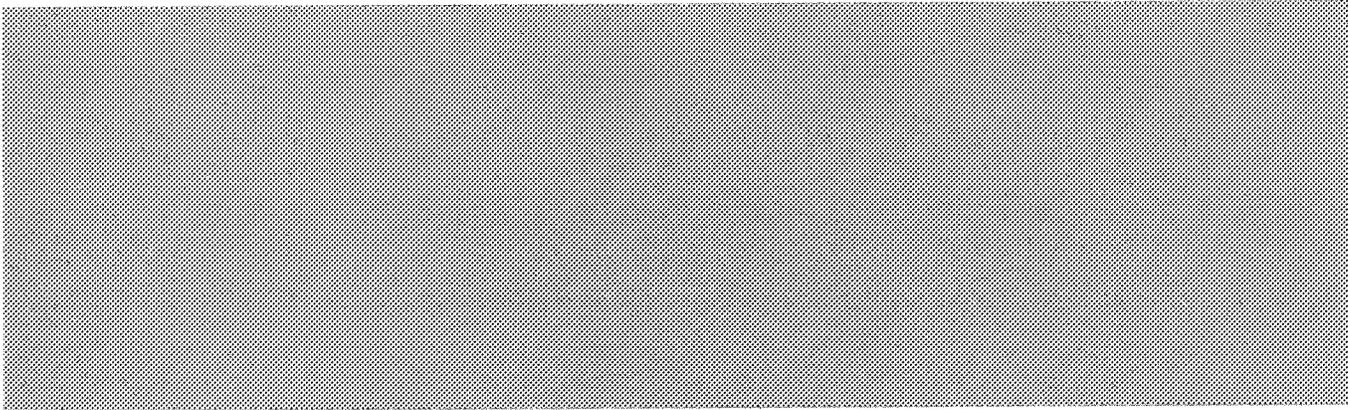
- The NCSBN states, "The purpose of the Compact is not to assist or inhibit the practice of tele nursing." (Published in correspondence to Governors and Attorneys General on May 4, 1998.) This statement is contrary to other NCSBN statements advocating in favor of the compact.
- Finally, the bill passed into law by the Wisconsin legislature includes nurse practitioners and nurse anesthetists (both are advanced practice nurses, [APNs]) for the first time in any compact proposal. Serious concerns have been raised about this latest development. An underlying assumption for the Multistate Licensure Compact proposal to work is that there is some semblance of uniformity among the state licensure laws. Nurse practitioner state scope of practice laws vary tremendously and their inclusion in the compact will only create more controversy and confusion about nursing practices, the compact, and the intentions of the NCSBN.

Again, thank you for the opportunity to discuss the position of NAPNAP and AWHONN as it pertains to the Multistate Licensure Compact Proposal. Please contact Matthew Williams at 202/544-1880 or Kristen LaRose at 202/261-2402, if you need further assistance.

Sincerely,

  
Debra Hardy Havens  
NAPNAP Washington Representative

  
Melinda Mercer Ray  
AWHONN Director of Health Policy and  
Legislative Affairs



**Appendix 4**

**Joint Working Group  
on Telemedicine  
Draft Paper  
on Credentialing**

# Certification on Telehealth: Should we do it?

A Draft Issues Paper Prepared for  
the Joint Working Group  
on Telemedicine  
May 6, 1999

- What are the advantages?
- What are the disadvantages?
- If the advantages outweigh the disadvantages, the following should be considered:

## ISSUES

National professional and provider organizations and government agencies are increasingly queried about whether there is a need for additional and/or official validation of practitioners' competency to engage in telehealth.

There is confusion about the meaning of the terms. For example, credentialing, certification, privileging and licensing are often used interchangeably to describe the validation of practitioners' competencies in telehealth. It is unclear whether these questions stem from financial, quality or safety concerns.

It is also unclear whether the questions about validation of competencies relate either solely to the equipment used or to the clinical care delivered. Additional complexity surrounds the relationship of the validation of individuals versus organizations.

## DISCUSSION

Many health care providers interested in telehealth services are trying to formulate responses to these issues and concerns. To open discussion, the following definitions are offered:

### LICENSURE:

The legal authority to practice

### CERTIFICATION:

Ensure that health care professionals meet defined standards for the specified practice.

Examples of commonly measured certification levels include:

- Tasks: Intravenous therapy
- Procedures: Advanced cardiac life support
- Bodies of knowledge (specialty): Informatics
- Expert practice: Medical specialty
- Credentialing: Documentation that supports professional education, training and experiences.

### PRIVILEGING:

The right to practice in a specific work environment with identified constraints.

Examples include:

- Admitting privilege
- Clinical privileges

### ACCREDITATION:

Acknowledgement granted to an organization that certain standards have been met.

### **Current Briefing**

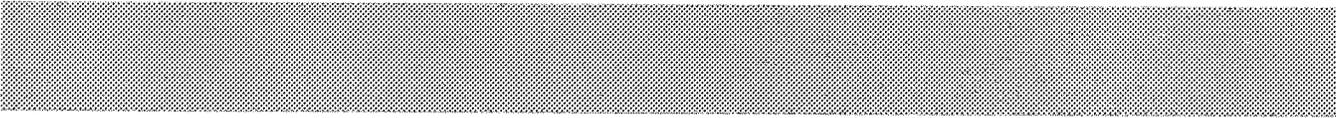
This briefing focuses on the relevant questions of certification and telehealth practice.

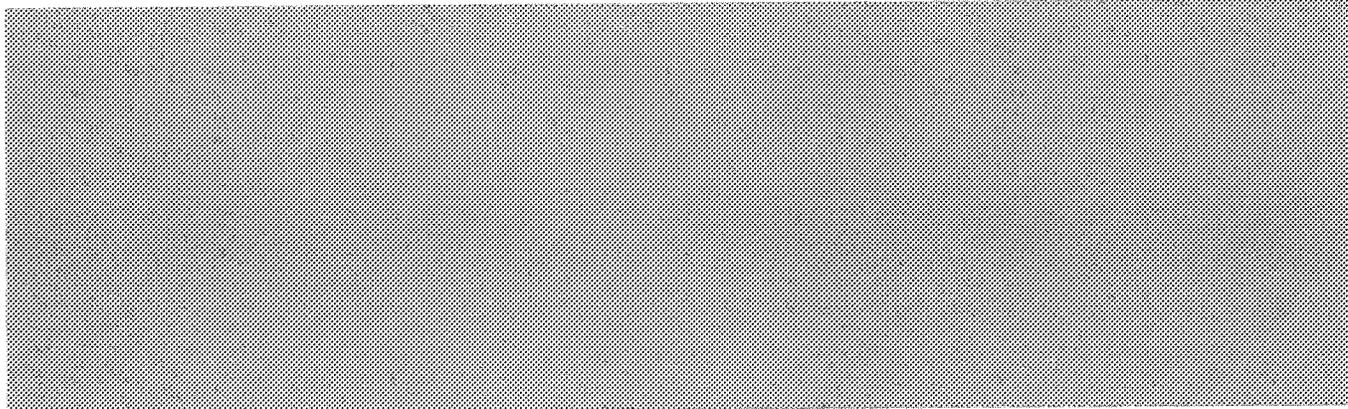
Factors to be considered include:

- What would be accomplished by certification in telehealth?
- What would be the rationale for certification?
- Would certification measure the knowledge domain or defined skill set?
- What dimensions of practice would be validated by certification?
- What would measure the practicality of the mechanism for certification?
- What would be the potential impact of certification on the health care consumer?
- Would the proposed certification be required for telehealth prior to practice?
- Would the certification be mandatory or voluntary?
- If certification is recommended, would there be an outside organization whose standards must be met?
- How would the stated need for certification be linked to measurable patient care outcomes?

### **Next Steps**

1. Each professional domain reviews the document and provides their position statement to the Joint Working Group on Telemedicine.
2. The JWGT synthesizes these responses.





## **Appendix 5**

# **Federal Drug Administration's Regulatory Role in Telemedicine**

# **U.S. DEPARTMENT OF COMMERCE**

**National Telecommunications and Information Administration**

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in consultation with  
The U.S. Department of Health and Human Services

## **Telemedicine Report to the Congress**



**January 31, 1997**

# SAFETY AND STANDARDS

## A. OVERVIEW

The use of advanced telecommunications technology to deliver health care brings with it a host of concerns about safety and effectiveness. For instance, does a cardiologist at an urban medical center, using an electronic stethoscope, get the proper sound resolution to effectively make a proper diagnosis during a teleconsult with a patient in a rural clinic? Will a technology that works for one specialty be equally safe for use in another specialty?

Many of the telemedicine systems in use today are adaptations of existing teleconferencing or desk top computer systems which were originally designed for purposes other than health care delivery. Although the system's individual components, such as software, may be regulated for safety, the entire telemedicine system is not necessarily evaluated objectively for its ability to safely provide diagnostic information.

Under the rubric of "telemedicine" falls a wide range of technologies and applications. This diversity poses a significant challenge to establishing standards for safe or efficacious practice, especially in light of the paucity of objective evaluative studies. Moreover, telemedicine technology is changing so rapidly that there are few formal standards or benchmarks to guide its use or technological development. This lack of standards has implications for telemedicine quality, safety, efficiency, effectiveness, privacy, investment and security. Since standards encompass such a broad range of telemedicine issues, we can only highlight some of those related to safety in this chapter.

It is clear that the lack of educational and clinical practice guidelines as well as technical standards in telemedicine can lead to practices or situations that could adversely affect patient safety. For example, lack of technical standards can lead to the purchase of equipment that cannot communicate with other equipment and does not provide adequate images for clinical decision-making. Without appropriate technical standards, the accuracy of data that is compressed and decompressed in transmission may be compromised. Technical standards for telecommunications or equipment infrastructure also have implications for safety. For example, if the telecommunications infrastructure is not reliable and there are no redundancies built in, patients may be at risk if the system unexpectedly fails at a critical moment. Inadequate educational and clinical guidelines can result in poor training of practitioners whose grasp of modern information and telecommunications technologies is essential to quality care.

## *Telemedicine Report to Congress*

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While most of the players in the telemedicine arena concur on the need for standards, there is less agreement on how to get there. It is hard to gain consensus, especially in the evolving field of telecommunications and with a variety of specialties involved in developing educational and clinical practice guidelines.

Given all these concerns, the Federal government has a legitimate interest in protecting the public from unsafe and untested medical technologies, while minimizing unnecessary regulatory delays in bringing to market life-saving or cost-saving technologies. The U.S. Federal Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is the lead agency with responsibility for protecting the public against unsafe medical devices. With respect to telemedicine, the FDA is responsible for ensuring the safety and effectiveness of telemedicine devices marketed in the United States. However, in telemammography, the FDA plays a broader role. (See Box 25)

### **Box 25: Mammography Quality Standards Act (MQSA) and Telemammography**

The MQSA of 1992 gives the Food and Drug Administration (FDA) a special role to play in the regulation of mammography, including the regulation of personnel, equipment, practices, and procedures in use in mammography facilities. The Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs (OHIP) will be responsible for the interpretation and development of standards where necessary to make them specifically applicable to telemammography as that becomes a viable modality.

The FDA's CDRH has prepared a White paper in response to a request from the JWGT entitled: "Telemedicine-Related Activities", that outlines its current telemedicine activities<sup>39</sup>. The FDA has also sponsored a public forum to discuss the potential role of the FDA in the regulation of software for clinical decision making. The regulation of software is an area of controversy, with some arguing for a greater FDA role in assuring the safety of the public and others arguing that the FDA will stifle innovation.

This chapter will discuss the Federal regulatory role including device evaluation as well as the collaborative process that has heretofore helped to guide the use of new medical equipment. In

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<sup>39</sup> The White paper is available on the World Wide Web at: <http://www.fda.gov/cdrh/telemed.html>

## *Safety and Standards*

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addition, it will briefly touch upon some of the concerns arising from the lack of generally accepted standards in this field

### **B. THE FDA REGULATORY ROLE**

The FDA has the authority to regulate medical devices intended for human use<sup>40</sup> However, the advent of telemedicine has created some new challenges for the agency One of the first questions is whether telemedicine systems should be considered medical devices. The FDA 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 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 purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes*<sup>41</sup>

Broadly speaking, telemedicine systems fall within this definition. The FDA places all medical devices into a series of regulatory classes based on the level of control necessary to assure safety and effectiveness of the devices<sup>42</sup> However, medical devices, including those used in telemedicine, vary widely in their complexity and degree of risk or benefits Consequently, they do not all need the same degree of regulation.

To coordinate its telemedicine efforts, the FDA recently designated the Division of Reproductive, Abdominal, Ear, Nose, and Throat and Radiological Devices (DRAERD) to take the

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40 *The Medical Device Amendments of 1976 (P L 94-295) and the Safe Medical Device Amendments of 1990 (P L 101-629)*

41 *The Federal Food, Drug, and Cosmetic Act, Sec 201 [321 of US Code title 21] (h)*

42 (1996). *Regulation of Medical Devices et al* III-5

## *Telemedicine Report to Congress*

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lead role in reviewing telemedicine devices. This gives manufacturers and professional organizations a central location within the agency to answer specific questions related to telemedicine devices. As with other medical devices, the regulatory process involves pre-market review of new or original devices, post-market surveillance, and quality systems assessment.

### **Box 26: Defining the FDA's Role in Software Regulation**

Some stand-alone software products with telemedicine applications fit the definition of a medical device as described in FDA draft policies developed in the late 1980s. Efforts are underway to develop a clear FDA policy for the regulation of medical software devices that is rational and risk-based.

The FDA plans to develop these policies using open forums with participation from industry and the clinical and scientific communities. For example, on September 3-4, 1996, the FDA and NLM held a public workshop attended by over 600 participants from industry, research institutes and government to discuss issues related to FDA regulation of software.

Information about the workshop can be found at: <http://www.fda.gov/cdrh/ost/nuswpole.html>

In December, 1996, the FDA proposed a classification for medical image management devices in the Federal Register. The proposal establishes a framework for the regulation of these devices and exempts some low-risk devices from certain regulatory requirements.

Of particular interest are Picture Archiving Communications Systems or PACS. Although most frequently associated with teleradiology, these systems have functions that are often the linchpin of most clinical telemedicine systems. PACS software organizes data files and provides image processing functions such as filtering (e.g., edge enhancement), measurement (e.g., distance, area and volume determinations), and special image (3D surface and volume rendering). These technical capabilities lie at the heart of most telemedicine systems that handle medical images. A summary of the proposed classification is available on the World Wide Web at: <http://www.fda.gov/cdrh/fr1202as.html>.

### **C. A SHARED ROLE**

The FDA also works with other Federal agencies, health professional groups and manufacturers to encourage the development of technical standards, clinical guidelines and professional protocols

## *Safety and Standards*

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for safety. Manufacturers and FDA representatives typically work together to develop standards for equipment construction and design that ensure safety in its use for health care.

The health care community is responsible for how equipment is used and how professional protocols and training are standardized. Physicians, nurses, and professional societies, such as the American College of Radiology (ACR), will typically establish standards that help guide the use of new equipment. As a result, the FDA plays a role of partner and ratifier by working with private sector groups to help set standards and guidelines. This applies to equipment standards, process standards (such as for developing software), and efforts to develop standard terminology for devices and procedures.

Although there has been slow progress on the clinical practice side in developing guidelines, some movement in the development of telemedicine technical communication standards has been made. One of the few breakthroughs in the image communication area is the creation of a uniform set of communication standards called DICOM (Digital Imaging and Communications in Medicine) by the American College of Radiology (ACR) and the National Electronic Manufacturers Association (ACR/NEMA).

In the area of health care informatics, several Federal Agencies are beginning to address standard issues. For example, the FDA and the Agency for Health Care Policy and Research (AHCPR) have been participating in an effort to coordinate health care informatics standards activities in the United States and to encourage international cooperation in related standards activities. Likewise, the National Library of Medicine (NLM) is heavily involved in sponsoring the development of data standards and uniform practices for effective transmission, aggregation, and integration of health care, public health and research data. And finally, Congress has turned its attention to this issue through the Kennedy-Kassebaum Health Insurance Portability and Accountability Act of 1996 by mandating the development and adoption of standards for electronic exchanges of health information for administrative purposes.<sup>43</sup>

Other agencies are beginning to test the technical reliability of telemedicine systems. Currently, the VA operates a laboratory to assess the efficacy and technical reliability of new health care technologies. Similarly, the Open Systems Laboratory at Lawrence Livermore Laboratories provides objective assessment of computer equipment. At the Department of Commerce, the National Institute of Standards and Technology (NIST) has an active program in conformance testing against industry

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43 House Resolution 3103

## *Telemedicine Report to Congress*

### **Box 27: FDA Outreach**

The FDA does more than regulate devices; it also conducts research and collaborates with other groups. For instance the FDA works with several other agencies and groups in telemedicine-related activities such as:

The Technology Transfer Taskforce (T3) works with the Advanced Research Projects Agency (ARPA) and its contractors regarding the pre-market approval process for telemedicine devices.

The CDRH staff works with the U.S. Public Health Service Office on Women's Health and Intelligence Community Working Group on the transfer of intelligence community technology for medical use. In October, the agency sponsored a conference on this issue entitled "The Transfer of Defense, Intelligence, Space and Energy Technologies to the Early Detection and Control of Cancers in Women."

standards. It develops test methods for software quality and measurement methods for electronics and manufactured products, works with integration issues and the NII, and is in charge of the National Voluntary Laboratory Accreditation Program.

In the clinical practice area, only the ACR has developed practice guidelines—for teleradiology (See Box 28 ). Both the American Medical Association (AMA), which has endorsed telemedicine as a solution to access-to-care problems, and the American Telemedicine Association (ATA) have studied a number of issues related to telemedicine and have urged medical specialty societies to develop appropriate practice parameters. The American Academy of Ambulatory Nurses is

### **Box 28: The ACR Teleradiology Standard**

The American College of Radiology defines teleradiology as "the electronic transmission of radiological images from one location to another for the purposes of interpretation and or consultation." Other elements of this ACR teleradiology standard are:

- Goals
- Qualification of Personnel
- Equipment Guidelines
- General Guidelines
- Licensing, Credentialing and Liability
- Communication
- Quality Control for Teleradiology
- Quality Improvement

## *Safety and Standards*

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completing work on practice standards for nurses using telephones to provide health care and the American Nurses Association is currently developing practice standards and guidelines for nurses practicing telehealth

While these efforts represent a starting point, much work remains. In the absence of any formal guidelines, it is left up to each clinician to ensure the quality of diagnostic and therapeutic capabilities so that the safety of the patient is in no way jeopardized by the use of telemedicine.

Few studies have been conducted to examine what technologies are most effective for particular health care practices and it is these kind of clinical trials and evaluation efforts that form the basis for practice guidelines. As a result, some health care providers have been reluctant to use telemedicine because of the lack of established clinical practice guidelines for any range of potential specialty applications.

### **D. NEXT STEPS**

Ensuring safety in telemedicine is a shared responsibility of the Federal government and private sector groups such as clinician organizations and equipment manufacturers. The FDA attempts to ensure a degree of safety through its device evaluation process. The agency also works with manufacturers and professional organizations to set standards for equipment and practice. However, the field of telecommunications and its application for health care is changing rapidly as new advances are made. The role of the Federal government in ensuring safety and effectiveness in telemedicine is still being defined. Some critics have charged that undue regulatory constraints may hamper development in this field. Others claim the FDA needs a more defined role to ensure the safety of patients being treated in telemedicine.

On an ongoing basis, the JWGT will work with the FDA, the FCC Advisory Committee on Telecommunications and Health Care as well as private sector groups to identify new issues of telemedicine safety and effectiveness concerns as they emerge. In addition:

- In the coming year, the JWGT will explore the economic and logistic feasibility of expanding the efforts of the VA, NIST, and the Open Systems Laboratory at Lawrence Livermore Labs as well as others to provide a technical assessment capability of telemedicine technologies that would be available to all Federal agencies and their grantees. JWGT will also explore similar efforts in the private and public sectors with outside groups such as the HOST labs (Healthcare

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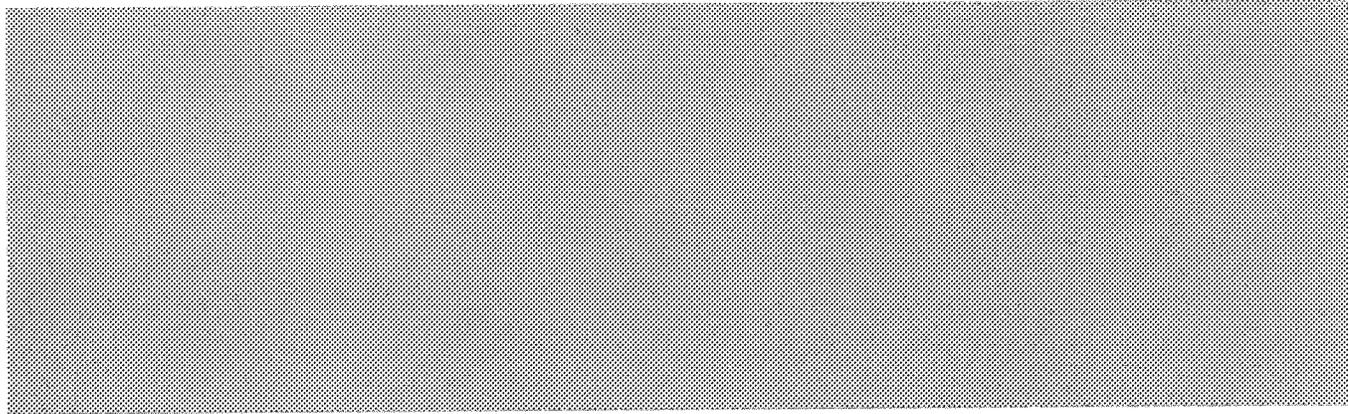
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Open Systems & Trials), an organization of Federal, state university, and private sector laboratories.

### **Box 29: FCC Group Emphasizes Need for Standards**

The FCC Advisory Committee on Telecommunications and Health Care put a high priority on standards development, saying: "It is important that policies are in place to encourage interoperability among the various equipment providers ... Similarly, for teleradiology applications, dental imaging, microscopic slide and endoscopy images, the use of DICOM standards should be encouraged for the image acquisition and processing equipment. DICOM is now being applied in multiple medical specialties, and the FCC should encourage continued discussion of DICOM as a basic communications device standard. The FCC should work with other agencies of the Federal government and the private sector to ensure interoperability."

- Over the next 12 months, the JWGT will be working with other subgroups within the Data Council and several outside groups to support the development of an agenda for establishing standards or guidelines for telemedicine.
- The JWGT will also work with the FCC Advisory Committee and other appropriate bodies in both telecommunications and telemedicine equipment on interoperability issues.



## **Appendix 6**

# **FCC Rural Health Care Program— A Short History**



## OVERVIEW

Recent technical advances in telecommunications allow telemedicine providers to receive clearer images with faster delivery on lower bandwidth equipment than just a few years ago. For example, advances in digital compression technology allow a telemedicine provider to photograph a skin graft using an off-the-shelf digital camera. The resulting high resolution image can be loaded into a computer and emailed over the Internet using a standard POT (Plain Old Telephone) line to a dermatologist across the globe, who can download the image for consultation. Two-way interactive real time video conferencing still requires higher bandwidth than such “store-and-forward” applications, but compression technology has also made it possible to transmit video over much lower bandwidth than in the past.

While these technological advances have lowered bandwidth requirements and equipment costs, high transmission cost continues to deter telemedicine, particularly in rural areas of the United States. While it may be only a few years away, competition in telecommunications service has not yet reached much of rural America and transmission cost is still a significant part of a rural telemedicine project’s overall budget. Competition was a theme of the landmark Telecommunications Act of 1996 (the Act), which provided a blueprint for major changes in the telecommunications industry, such as opening up competition between long distance carriers and the Regional Bell Operating Companies. In particular, the Act provided that rural health care providers (HCPs), should have access to advanced telecommunications services at reduced rates.

## BACKGROUND

Section 254 of the 1996 Telecommunications Act required the Federal Communications Commission (FCC) to explore actions that would provide advanced telecommunications services at reduced rates to rural HCPs, by requiring that:

*“A telecommunications carrier shall, upon receiving a bonafide request, provide telecommunications services which are necessary for the provision of health care services in a State, . . . at rates that are reasonably comparable to rates charged for similar services in urban areas in that State.”*

To implement this requirement, the FCC held public hearings on rural telemedicine issues and established the Advisory Committee on Telecommunications and Health Care. The Advisory Committee was composed of telecommunications, telemedicine, and rural health care experts who advised the FCC and the Joint Board on Universal Service support. The committee developed a report that, among other things, defined what is “rural,” recommended what telecom services should be covered, and provided a “market basket” of essential telemedicine applications for rural areas.

On May 8, 1997, the FCC released a “Report and Order on Universal Service” (the Order) to implement Section 254 of the Act. The Order outlined the funding mechanism to support telecommunications services used by rural HCPs, defined eli-

gible services, and stipulated that total annual support for rural HCPs could not exceed \$400 million. Specifically, the FCC provided that all rural public and non-profit HCPs could obtain telecommunications services at rates comparable to those paid for similar services in the nearest urban area of more than 50,000 residents in the rural HCP's state. Eligible services were defined as any telecommunications service "necessary for the provision of health care" with a bandwidth up to and including 1.544Mbps. Telecommunications carriers (telcos) were required to charge rural HCPs a rate no higher than the highest tariffed or publicly available rate for that service in an urban setting. Although the FCC incorporated many of the Advisory Committee's recommendations such as support for up to 1.544 MBPS, it rejected some recommendations such as infrastructure support or unlimited support for toll-free access to the Internet.

### **Rural Health Care Corporation**

In September 1997, the FCC established the non-profit Rural Health Care Corporation (RHCC), to implement and administer the rural health care program. Support in the first year of the program was limited to \$100 million. As provided by the FCC, rural HCPs and telcos providing service were required to submit several forms to qualify for subsidies. An HCP was first to submit Form 465, which allowed the HCP to solicit bids for telecommunications services and to certify their eligibility for the program. After a 28-day waiting period, during which time Form 465 was posted on the RHCC website to receive bids from competing telcos, the HCP could choose among the competing bids. The HCP was also free to solicit bids outside of the RHCC process, which often was necessary because few HCPs received bids explicitly as a result of posting on the RHCC website. The HCP could then complete Form 466 for their selected telecommunications carrier(s), which was submitted, jointly with Form 468, as completed by the selected carrier(s). RHCC could not process Form 466 without an accompanying Form 468 and a copy of a service contract or tariff number/agreement.

### **Programmatic barriers**

In the program's first year, three issues proved to be major stumbling blocks:

- **The application process was complex**, requiring multiple steps and involvement of a local telephone company.
- **Long distance (non-Eligible Telecommunications Carriers or non-ETCs) were excluded from the program**, making it generally impossible for rural health care providers to receive support for circuits that crossed Local Access and Transport Areas (LATAs)
- **The FCC's benchmark used to calculate subsidies reflected "list" rather than "discount" rates** that were often paid by urban health care providers. This made the difference between the rural rate and the urban benchmark small or negative, resulting in little or no subsidy for some rural health care providers.

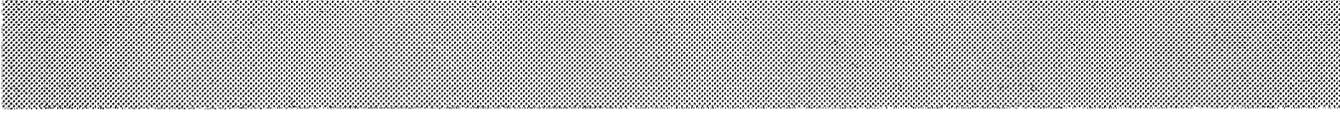
Specifically, the urban benchmark used to calculate subsidies reflected “month-to-month” tariffed rates rather than longer term discounted rates often available to customers that made multi-year commitments. For example, large urban hospitals often signed longer-term contracts such as a 3-year tariff for which the telco waived its installation fee and charged a lower rate than it would for a customer that paid a month-to-month rate. Given the disincentives posed by these barriers, a number of rural HCPs applied to RHCC, but did not follow-through and complete the application process. Furthermore, since the rural telcos had to complete their part of the application process, some rural HCPs reported expending substantial effort educating local telcos about the program or getting the telco, which had no local competition, to complete the application form.

In addition to these issues, in May 1998, the FCC voted to merge the RHCC and the Schools and Libraries Corporation (SLC) into the Universal Service Administrative Company (USAC). USAC had responsibility for the rural health care program, the schools and libraries program, the high cost program, and the low-income program. RHCC became the Rural Health Care Division (RHCD) of USAC. Further delay in getting the RHCD program started resulted from RHCD’s need to complete two pre-disbursement audits prior to making any funding commitments. The FCC approved the second audit on June 4, 1999, and RHCD issued its first funding commitments on June 25, 1999, five days before the end of the first 18-month program year. Also in May, 1999, in response to USAC’s estimate of current eligible program demand, the FCC reduced the RHCD funding cap to \$12 million for the second program year (July 1, 1999 to June 30, 2000).

#### **RECENT FCC REFORMS TO THE RHC PROGRAM**

In November 1999, the FCC released the Fourteenth and Fifteenth Orders on Reconsideration of the Universal Service Order, which addressed several major concerns about the Rural Health Care Program. These reforms were based in part, on recommendations of USAC, OAT and its grantees, (OAT filing with the FCC), and the Secretary of Health and Human Services (DHHS) in her letter of September 8, 1999 to the Chairman of the FCC, plus other interested parties. Among other things, the Orders:

- Expanded the list of telecommunication carriers able to participate in the program to include non-ETC (long distance) carriers;
- Streamlined the application process;
- Changed the discount calculation to distance based charges paid by rural healthcare providers rather than a comparison of urban and rural published tariffs; and
- Eliminated bandwidth and quantity limits so that any bandwidth and any number of services could be supported.

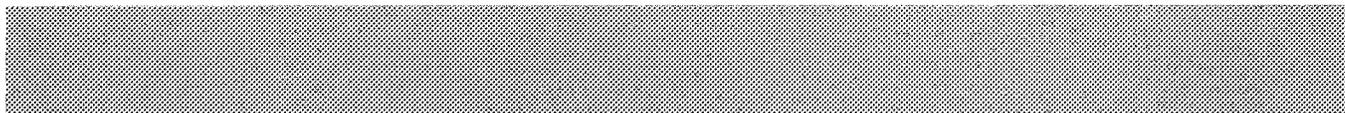


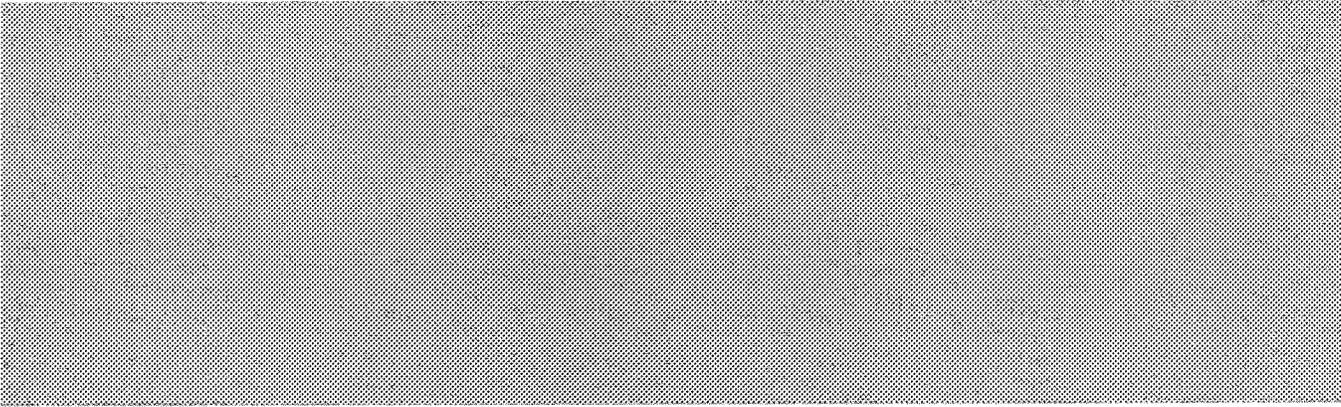
Prior to the 14<sup>th</sup> Order, virtually all ETCs were local telephone companies; thus rural HCPs could not receive support for discounted services from long distance companies, which often provided the bulk of their telecommunications services. The 14<sup>th</sup> Order allowed RHCD to provide program year 1 support to applicants that had been using a non-ETC, (i.e. applicants that had not already received support for an alternate telco). RHCD extended the deadline for such rural HCPs to complete year 1 funding requests, and 25% more rural HCPs received \$1.5 million more support in year 1, than would have been supported without the 14<sup>th</sup> Order. In total, 483 rural HCPs received \$3.4 million in telecommunications support for the first program year (January 1, 1998 through June 30, 1999).

The FCC's 15<sup>th</sup> Order, effective July 1, 2000, allowed USAC to support any commercially available telecommunications service regardless of bandwidth. In the past, USAC was limited to supporting a 1.544Mbps (T-1) line or some combination of lesser services. This reform streamlined the application process and allowed rural HCPs to choose either higher or lower bandwidth than T-1 for their programs. However, in some areas, such as Alaska, South Dakota, Montana and other states where such services as ISDN are not generally available, this reform may not be as beneficial to rural HCPs as in other areas where telecommunications companies offer a wide variety of services. According to the FCC, any telecommunications service, including wireless service, will be allowed as long as it is used for telehealth care delivery services and as long as a telecommunications carrier provides the service.

The 15<sup>th</sup> Order also changed the way the discount is calculated. As a result of the 15<sup>th</sup> Order, RHCD now calculates support based on actual distance based charges paid by the HCP rather than on published tariffs. This change should streamline the application process and provide discounts that more closely reflect the difference between rates paid by urban and rural HCPs.

In the third year of the program, the RHCD has funded four hundred and ten (410) eligible telemedicine health care providers \$6.1 million as of November 2000. While some telemedicine practitioners can benefit from the FCC discounts, they are no substitute for the possible economic benefits that competition in the area could bring. Competition for telecommunication services has not yet reached rural America where it is most needed. Cable, wireless and satellite or other cheaper new technologies may eventually provide the needed competition to bring the cost of transmission down. In the meantime, the RHCD is one of the few ways that eligible telemedicine networks can reduce their monthly transmission costs.





## **Appendix 7**

# **U.S. Department of Health & Human Services Fact Sheet on Final HIPAA Privacy Rules**

# HHS Fact Sheet



U.S. Department of Health and Human Services

[www.hhs.gov/news](http://www.hhs.gov/news)

December 20, 2000

Contact: HHS Press Office  
(202) 690-6343

## PROTECTING THE PRIVACY OF PATIENTS' HEALTH INFORMATION SUMMARY OF THE FINAL REGULATION

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**Overview:** *Each time a patient sees a doctor, is admitted to a hospital, goes to a pharmacist or sends a claim to a health plan, a record is made of their confidential health information. For many years, the confidentiality of those records was maintained by our family doctors, who kept our records sealed away in file cabinets and refused to reveal them to anyone else. Today, the use and disclosure of this information is protected by a patchwork of state laws, leaving large gaps in the protection of patients' privacy and confidentiality. There is a pressing need for national standards to control the flow of sensitive patient information and to establish real penalties for the misuse or disclosure of this information.*

*President Clinton and Congress recognized the need for national patient record privacy standards in 1996 when they enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA). That law gave Congress until August 21, 1999, to pass comprehensive health privacy legislation. After three years of discussion in Congress without passage of such a law, HIPAA provided HHS with the authority to craft such privacy protections by regulation. Following the principles and policies laid out in the recommendations for national health information privacy legislation the Administration submitted to Congress in 1997, the Administration drafted regulations to guarantee patients new rights and protections against the misuse or disclosure of their health records and the President and Secretary Donna E. Shalala released them in October of last year. During an extended comment period, HHS received, electronically or on paper, more than 52,000 communications from the public.*

*This final rule provides the first comprehensive federal protection for the privacy of health information. However, because of the limitations of the HIPAA statute, these protections do not fully achieve the Administration's goal of a seamless system of privacy protection for all health information. Members of both parties in Congress will need to pass meaningful, comprehensive privacy protection for American patients that would extend the reach of the standards being finalized today to all entities that hold personal health information.*

### COVERED ENTITIES

As required by HIPAA, the final regulation covers health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions (e.g., electronic billing and funds transfers) electronically.

### INFORMATION PROTECTED

All medical records and other individually identifiable health information held or disclosed by a covered entity in any form, whether communicated electronically, on paper, or orally, is covered by the final regulation.

## **COMPONENTS OF THE FINAL RULE**

The rule is the result of the Department's careful consideration of every comment and reflects a balance between accommodating practical uses of individually identifiable health information and rendering maximum privacy protection of that information.

### **CONSUMER CONTROL OVER HEALTH INFORMATION**

Under this final rule, patients have significant new rights to understand and control how their health information is used.

- Patient education on privacy protections. Providers and health plans are required to give patients a clear written explanation of how they can use, keep, and disclose their health information.
- Ensuring patient access to their medical records. Patients must be able to see and get copies of their records, and request amendments. In addition, a history of most disclosures must be made accessible to patients.
- Receiving patient consent before information is released. Patient authorization to disclose information must meet specific requirements. Health care providers who see patients are required to obtain patient consent before sharing their information for treatment, payment, and health care operations purposes. In addition, specific patient consent must be sought and granted for non-routine uses and most non-health care purposes, such as releasing information to financial institutions determining mortgages and other loans or selling mailing lists to interested parties such as life insurers. Patients have the right to request restrictions on the uses and disclosures of their information.
- Ensuring that consent is not coerced. Providers and health plans generally cannot condition treatment on a patient's agreement to disclose health information for non-routine uses.
- Providing recourse if privacy protections are violated. People have the right to complain to a covered provider or health plan, or to the Secretary, about violations of the provisions of this rule or the policies and procedures of the covered entity.

### **BOUNDARIES ON MEDICAL RECORD USE AND RELEASE**

With few exceptions, an individual's health information can be used for health purposes only.

- Ensuring that health information is not used for non-health purposes. Patient information can be used or disclosed by a health plan, provider or clearinghouse only for purposes of health care treatment, payment and operations. Health information cannot be used for purposes not related to health care - such as use by employers to make personnel decisions, or use by financial institutions - without explicit authorization from the individual.
- Providing the minimum amount of information necessary. Disclosures of information must be limited to the minimum necessary for the purpose of the disclosure. However, this provision does not apply to the transfer of medical records for purposes of treatment, since physicians, specialists, and other providers need access to the full record to provide best quality care.
- Ensuring informed and voluntary consent. Non-routine disclosures with patient authorization must meet standards that ensure the authorization is truly informed and voluntary.

## **ENSURE THE SECURITY OF PERSONAL HEALTH INFORMATION**

The regulation establishes the privacy safeguard standards that covered entities must meet, but it leaves detailed policies and procedures for meeting these standards to the discretion of each covered entity. In this way, implementation of the standards will be flexible and scalable, to account for the nature of each entity's business, and its size and resources. Covered entities must:

- Adopt written privacy procedures. These must include who has access to protected information, how it will be used within the entity, and when the information would or would not be disclosed to others. They must also take steps to ensure that their business associates protect the privacy of health information.
- Train employees and designate a privacy officer. Covered entities must provide sufficient training so that their employees understand the new privacy protections procedures, and designate an individual to be responsible for ensuring the procedures are followed.
- Establish grievance processes. Covered entities must provide a means for patients to make inquiries or complaints regarding the privacy of their records.

## **ESTABLISH ACCOUNTABILITY FOR MEDICAL RECORDS USE AND RELEASE**

Penalties for covered entities that misuse personal health information are provided in HIPAA.

- Civil penalties. Health plans, providers and clearinghouses that violate these standards would be subject to civil liability. Civil money penalties are \$100 per incident, up to \$25,000 per person, per year, per standard.
- Federal criminal penalties. There would be federal criminal penalties for health plans, providers and clearinghouses that knowingly and improperly disclose information or obtain information under false pretenses. Penalties would be higher for actions designed to generate monetary gain. Criminal penalties are up to \$50,000 and one year in prison for obtaining or disclosing protected health information; up to \$100,000 and up to five years in prison for obtaining protected health information under "false pretenses"; and up to \$250,000 and up to 10 years in prison for obtaining or disclosing protected health information with the intent to sell, transfer or use it for commercial advantage, personal gain or malicious harm.

## **BALANCING PUBLIC RESPONSIBILITY WITH PRIVACY PROTECTIONS**

After balancing privacy and other social values, HHS is establishing rules that would permit certain existing disclosures of health information without individual authorization for the following national priority activities and for activities that allow the health care system to operate more smoothly. All of these disclosures have been permitted under existing laws and regulations. Within certain guidelines found in the regulation, covered entities may disclose information for:

- Oversight of the health care system, including quality assurance activities
- Public health
- Research, generally limited to when a waiver of authorization is independently approved by a privacy board or Institutional Review Board
- Judicial and administrative proceedings
- Limited law enforcement activities
- Emergency circumstances
- For identification of the body of a deceased person, or the cause of death
- For facility patient directories

- For activities related to national defense and security

The rule permits, but does not require these types of disclosures. If there is no other law requiring that information be disclosed, physicians and hospitals will still have to make judgments about whether to disclose information, in light of their own policies and ethical principles.

### **SPECIAL PROTECTION FOR PSYCHOTHERAPY NOTES**

Psychotherapy notes (used only by a psychotherapist) are held to a higher standard of protection because they are not part of the medical record and never intended to be shared with anyone else. All other health information is considered to be sensitive and treated consistently under this rule.

**EQUIVALENT TREATMENT OF PUBLIC AND PRIVATE SECTOR HEALTH PLANS AND PROVIDERS.** The provisions of the final rule generally apply equally to private sector and public sector entities. For example, both private hospitals and government agency medical units must comply with the full range of requirements, such as providing notice, access rights, requiring consent before disclosure for routine uses, establishing contracts with business associates, among others.

### **CHANGES FROM THE PROPOSED REGULATION**

- Providing coverage to personal medical records in all forms. The proposed regulation had applied only to electronic records and to any paper records that had at some point existed in electronic form. The final regulation extends protection to all types of personal health information created or held by covered entities, including oral communications and paper records that have not existed in electronic form. This creates a privacy system that covers virtually all health information held by hospitals, providers, health plans and health insurers.
- Requiring consent for routine disclosures. The final rule requires most providers to obtain patient consent for routine disclosure of health records, in addition to requiring special patient authorization for non-routine disclosures. The earlier version had proposed allowing these routine disclosures without advance consent for purposes of treatment, payment and health care operations (such as internal data gathering by a provider or health care plan). However, most individuals commenting on this provision, including many physicians, believed consent for these purposes should be obtained in advance, as is typically done today. The final rule retains the new requirement that patients must also be provided detailed written information on privacy rights and how their information will be used.
- Allowing disclosure of the full medical record to providers for purposes of treatment. For most disclosures, such as information submitted with bills, covered entities are required to send only the minimum information needed for the purpose of the disclosure. However, for purposes of treatment, providers need to be able to transmit fuller information. The final rule gives providers full discretion in determining what personal health information to include when sending patients' medical records to other providers for treatment purposes.
- Protecting against unauthorized use of medical records for employment purposes. Companies that sponsor health plans will not be able to access the personal health information held by the plan for employment-related purposes, without authorization from the patient.

### **COST OF IMPLEMENTATION**

Recognizing the savings and cost potential of standardizing electronic claims processing and protecting privacy and security, the Congress provided in HIPAA 1996 that the overall financial impact of the

HIPAA regulations reduce costs. As such, the financial assessment of the privacy regulation includes the ten-year \$29.9 billion savings HHS projects for the recently released electronic claims regulation and the projected \$17.6 billion in costs projected for the privacy regulation. This produces a net savings of approximately \$12.3 billion for the health care delivery system while improving the efficiency of health care as well as privacy protection.

### **PRESERVING EXISTING, STRONG STATE CONFIDENTIALITY LAWS**

Stronger state laws (like those covering mental health, HIV infection, and AIDS information) continue to apply. These confidentiality protections are cumulative; the final rule sets a national "floor" of privacy standards that protect all Americans, but in some states individuals enjoy additional protection. In circumstances where states have decided through law to require certain disclosures of health information for civic purposes, we do not preempt these mandates. The result is to give individuals the benefit of all laws providing confidentiality protection as well as to honor state priorities.

### **THE NEED FOR FURTHER CONGRESSIONAL ACTION**

HIPAA limits the application of our rule to the covered entities. It does not provide authority for the rule to reach many persons and businesses that work for covered entities or otherwise receive health information from them. So the rule cannot put in place appropriate restrictions on how such recipients of protected health information may use and re-disclose such information. There is no statutory authority for a private right of action for individuals to enforce their privacy rights. We need Congressional action to fill these gaps in patient privacy protections.

### **IMPLEMENTATION OF THE FINAL REGULATION**

The final regulation will come into full effect in two years. The regulation will be enforced by HHS' Office for Civil Rights, which will provide assistance to providers, plans and health clearinghouses in meeting the requirements of the regulation - including a toll free line to help answer questions: 1-866-OCR-PRIV (1-866-627-7748). The TTY number is 1-866-788-4989. A Web site on the new regulation will also be available at <http://www.hhs.gov/ocr>.

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Note: For other HHS Press Releases and Fact Sheets pertaining to the subject of this announcement, please [click here](#) for our Press Release and Fact Sheet search engine at: <http://www.hhs.gov/search/press.html>.



U.S. Department of Health and Human Services  
Health Resources and Services Administration  
Office for the Advancement of Telehealth