

Telemedicine

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# Exploratory Evaluation of Rural Applications of Telemedicine Executive Summary

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## Overview

The Office of Rural Health Policy (ORHP), Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS), and other State and Federal governmental agencies have devoted considerable financial support to rural telemedicine demonstration projects. The projects are using modern telecommunication technology to improve access to health care for rural populations. ORHP has been involved in telemedicine since 1988 and currently funds 11 telemedicine projects through its Rural Telemedicine Grant program, a large demonstration project in West Virginia, and six telehealth projects through its Rural Health Outreach grant program. One of the missing pieces in assessing the value of telemedicine was a comprehensive study of the use of this technology throughout rural America. This project, which was the first nationwide survey of rural telemedicine (not limited to interactive video), examined the status of rural telemedicine. It also developed evaluation tools and methods for agencies and individual programs to use in assessing the contribution of telemedicine to rural health care delivery. As such, this study represents an early snapshot of a technology that is expanding rapidly both in technical capability and potential applications for health care.

Rural Telemedicine is in the earliest stages of development, but is expanding quickly. More than 40 percent of the telemedicine programs surveyed had been providing teleconsults for one year or less. Networks had an average of 9.3 facilities participating and many planned to expand. By the end of 1996, networks expected to have an average of 13 participating sites.

By the end of 1996, nearly 30 percent of rural hospitals will be using some sort of telemedicine technology to deliver patient care. Of these, 68 percent will offer only teleradiology.

Age of the telemedicine system and receipt of Federal funding were all positively and significantly associated with total utilization of the telemedicine system (clinical and nonclinical sessions combined). The strongest association was between utilization and age of the system--as facilities gain experience with telemedicine, utilization increases.

Some clinical applications appear to gain earlier acceptance in telemedicine than others. Radiology and cardiology were the most common clinical applications reported, followed by orthopedics, dermatology, and psychiatry. The most common nonclinical applications

were education, administrative meetings, and demonstrations of the system to health care personnel.



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## Evaluation Objectives

The *Exploratory Evaluation of Rural Applications of Telemedicine* was conceptualized by ORHP and conducted by Abt Associates, Inc., assisted by the University of Colorado. The objectives of the study included:

- Determining the current status of telemedicine in rural health care with respect to the number and types of systems in operation, levels of technology employed, types of specialty services provided, utilization of services, costs, and patient and provider acceptance.
- Exploring the effects of telemedicine on access to care, practitioner isolation, and the development of health care networks.
- Exploring the organizational factors (at facility, network, community and State levels) that aid or impede the successful development and implementation of telemedicine systems.
- Developing, testing, and refining data collection instruments that may be used in subsequent evaluation efforts.



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## Activities

The study design specified by ORHP included the following activities:

- Nationwide survey of all rural hospitals to identify those actively using telemedicine (summer 1995)
- Detailed follow-up survey of participants and their affiliates to describe uses of telemedicine; equipment and transmission media in use; funding sources and costs of telemedicine installations; volume of care being provided and volume of nonclinical uses of the systems; and use of telemedicine to fill gaps in specialty access in remote rural areas (Dec. 1995-Jan. 1996).
- Intensive site visits at four rural telemedicine programs to investigate issues not readily studied via a survey and to provide the context for the survey data.

The screening survey was mailed to all 2,472 non-Federal U.S. hospitals that are outside metropolitan areas, as defined by the U.S. Census. Those that did not respond were interviewed via telephone. The final response rate was 95 percent. All those who reported that they had some form of telemedicine capability, and all the telemedicine affiliates they named, became the sample for the follow-up survey. Affiliates included metropolitan medical centers, rural clinics, mental health centers, and nursing homes. Each target respondent received two instruments in the mail: one for programs that do only teleradiology and a longer questionnaire for those who have other telemedicine applications available beyond radiology. Respondents were asked to select, complete and return the

appropriate questionnaire. Again, nonrespondents were interviewed by telephone. The telephone follow-up portion of the sample were interviewed using an abbreviated instrument: they were not asked to obtain information from administrative or financial records because this is difficult to do in the course of a telephone interview. From the group of 558 active rural telemedicine sites and their affiliates, 499 (89 percent) completed the follow-up survey.



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## Response and Findings

The very high overall response rates were accompanied by significant item nonresponse on some survey questions. The most problematic were questions about the precise equipment in use (e.g., resolution of monitors), about billing practices, and about reimbursement for telemedicine sessions. Questions about the number of sessions and the percent that was for clinical vs. nonclinical purposes also appeared to be difficult for many sites to answer, largely because they did little session-level data collection beyond simple counts. The final chapter of this report recommends Amodel@ data collection tools, an encounter session form which could be aggregated annually (or more often), and a facility-level survey which could be conducted annually.

The following are additional key findings from the survey efforts and the case study investigations:

- Telemedicine networks were complex, with an average of four spoke sites, two hubs, and four facilities that both provided and received consults.
- Many rural hospitals were taking full advantage of the available technology. The equipment base was large, sophisticated, and growing quickly. Most rural telemedicine sites (excluding those doing only teleradiology) offered full-motion interactive video for live interviews, meetings, and educational sessions.
- Despite the growth and expansion of this technology, the cost of telemedicine remained high. The average equipment purchase, excluding switches and new lines, ranged from \$134,378 for spoke sites to \$287,503 for hub sites. Reported annual transmission costs were also high, ranging from an average of \$18,573 for spokes to \$80,068 for hubs.
- Utilization was low in the first years of most rural telemedicine programs. The average number of total sessions per month (clinical and nonclinical combined) was 24, with a median of 11. The median or typical telemedicine facility was conducting approximately one clinical session per week and 1-2 nonclinical sessions per week in early 1996.
- High costs, combined with low utilization in the early years of operation, yielded high unit costs. A teleconsult cost the median or typical hub site \$1,181, while the median spoke site spent \$476 per consult, exclusive of any reimbursement to clinicians.
- Federal and State grants were common sources of direct funding for telemedicine programs, and the majority of sites also received hospital financial support. Third-party reimbursement for telemedicine was elusive: fewer than 25 percent of hub facilities had successfully negotiated payment with insurance carriers and many had not yet undertaken such negotiations.
- Lack of reimbursement, lack of clinical standards, scheduling, and time commitment

remain challenges to further development and use of rural telemedicine.

The findings of this study confirmed many issues previously identified in grant projects relating to organizational challenges and barriers to expansion. At the same time, the survey pointed out some new developments in the field. First, most of the surveyed programs were quite new. This may in part explain the relatively low utilization figures reported on the survey, and the high resulting unit costs. It is important to note that those systems able to survive and expand experience higher utilization after the second year of operations. It is also clear that more rural hospitals were turning to telemedicine as a tool for improving health care delivery, despite the fact that there is limited reimbursement for these services from third-party payers.



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*Last Updated March 11, 1997*

# TELEMEDICINE REPORT TO CONGRESS

January 31, 1997

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## EXECUTIVE SUMMARY

Telemedicine, in one form or another, has been practiced for over thirty years. At the simplest level, a nurse providing clinical advice over the telephone is telemedicine. Today, however, we think of telemedicine applications that employ advanced image as well as audio capabilities. These technologies can range from high resolution still images (e.g., x-rays) to sophisticated interactive teleconferencing systems. Telemedicine now has the potential to make a difference in the lives of many Americans. For example, telemedicine can improve the delivery of health care in America by bringing a wider range of services such as radiology, mental health services and dermatology to communities and individuals in underserved urban and rural areas. In remote rural areas, where the distance between a patient and a health professional can be hundreds of miles, telemedicine can mean access to health care where little had been available before. In emergency cases, this access can mean the difference between life and death. In particular, in those cases where fast medical response time and specialty care are needed, telemedicine availability can be critical. In addition, telemedicine can also help attract and retain health professionals in rural areas by providing ongoing training and collaboration with other health professionals.

Given this potential, Congress has asked the Secretary of Commerce, in consultation with the Secretary of Health and Human Services and other appropriate departments and agencies, to submit a report on the use of advanced telecommunications services for medical purposes. Specifically, the Telecommunications Reform Act of 1996, requires a summary of the Joint Working Group on Telemedicine's (JWGT) activities as well as findings from federally-funded telemedicine studies and demonstrations. In addition, Congress requested that the report examine questions related to patient safety, the efficacy and quality of services provided and other legal, medical, and economic issues.<sup>(1)</sup>

## BACKGROUND

Before launching into a full discussion of telemedicine and its related topics, it is important to clarify the definition and scope of telemedicine. For the purposes of this report, "telemedicine" refers to the use of electronic communication and information technologies to provide or support clinical care at a distance. Various broader definitions of "telemedicine" have been previously proposed, such as the Institute of Medicine's<sup>(2)</sup> interpretation in its recent publication on telemedicine.

More broadly speaking, the term "telehealth" is often used to refer to a diverse group of health-related activities, such as health professional's education, community health education, public health, research, and administration of health services. Although this report primarily focuses on telemedicine, it should be noted that almost all of the telemedicine activities funded by the Federal agencies have some broader telehealth applications.

The telemedicine projects and networks now operating are just beginning to test the potential of telemedicine to deliver health care services, safely and efficiently. What is known today about telemedicine represents only an initial snapshot of a technology that is changing and expanding daily. Given that telemedicine is still in its early stages, the report's scope is limited to a current status report of federally-funded telemedicine studies and projects.

The concept for the JWGT began with Vice President Gore, who identified telemedicine as a key area requiring attention to ensure progress in the development of the National Information Infrastructure (NII). Since 1992, the Information Infrastructure Task Force, (IITF) under the leadership of the Department of Commerce (DOC), has examined broad innovative uses of the NII and coordinated NII initiatives throughout the Federal government. In early 1994, it created the Health Information

Application Working Group, with a subgroup that focused upon telemedicine.

In 1995, after the Vice President asked the Department of Health and Human Services (HHS) to take a greater leadership role in developing cost-effective health applications for the NII, the Commerce Department joined forces with HHS to form the Joint Working Group on Telemedicine, which is chaired by the acting director of the Office of Rural Health Policy, Health Resources and Services Administration (ORHP). Currently, the JWGT is a government-wide entity with a focus on telemedicine that has grown to more than eight member departments and agencies<sup>(3)</sup>.

The JWGT is charged with assessing the role of the Federal government in telemedicine and coordinating telemedicine activities across Federal cabinet agencies. Part of that task involves developing specific actions to overcome barriers to the effective use of telemedicine technologies. JWGT members are involved in several different aspects of telemedicine; each member agency bringing its own unique expertise to the table. Table B at the end of the summary, gives a brief outline of these activities.

## KEY ISSUES

The Joint Working Group has worked to educate its members through distributed material and presentations from both public and private sector groups that specialize in this field. These efforts have helped the group achieve greater consensus on a range of key issues. Some of these issues as well as those identified in the Group's work plan are highlighted below:

**Development of a Working Inventory of Federal Projects.** When the Vice President tasked the JWGT to report on current telemedicine projects funded by the Federal government, there was no comprehensive inventory of Federal telemedicine projects available. Therefore, the JWGT identified the development of a Federal inventory as a high priority activity. JWGT created an electronic inventory of Federal telemedicine activities that will be posted on the World Wide Web. The Telemedicine Gateway should be viewed as a prototype that demonstrates the usefulness of using the World Wide Web for maintaining distributed data bases across Federal agencies. The basic design of the inventory could be very useful to other initiatives that need to be tracked across Federal agencies.

**Evaluation.** Although many individuals believe strongly in the potential of telemedicine for providing cost-effective services, not much "hard data" is available to support that belief. Decision-makers want to know the value-added of telemedicine. Lack of solid evaluative information is a significant barrier to the deployment of telemedicine. In the past year, the JWGT has developed a framework for project evaluation. The framework allows federally-funded projects to share information with each other and may eventually facilitate cooperative evaluation efforts with private sector telemedicine projects. In addition, several JWGT members have funded evaluation studies and developed evaluation requirements for their federal telemedicine grantees so that comparative information can be gathered and analyzed. For example, the Defense Department (DoD) is evaluating some of its telemedicine demonstration projects, such as that in Bosnia; ORHP has funded, along with several other evaluation studies, a project to develop uniform data collection instruments; DOC's National Telecommunications and Information Administration (NTIA) recently released "*Lessons Learned from the Telecommunication and Information Infrastructure Assistance Program*," a report based on the experiences of its grantees.

**Safety/Standards.** Given telemedicine's rapid technological changes, most technical standards, and educational/clinical practice guidelines for telemedicine are either in the early developmental stages or non-existent. For example, with the exception of the American College of Radiology, which developed practice guidelines for teleradiology, there are no specialty-generated technical standards, protocols or clinical guidelines for telemedicine. This lack in standards may have serious implications for telemedicine safety and efficacy.

There are several groups in the process of generating clinical practice guidelines. Both the American Medical Association (AMA) 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 Care Nurses is currently developing practice standards for telephone-based nursing practice and the American Nurses Association is also in

## **STUDENT ISSUES**

Students at PSU need to be aware of the issues that effect them and take an active part in advocating for what matters most. We must stop fee hikes, improve campus safety, expand retention efforts, and mobilize our student body to work together on the issues that WE care about. One way to do this is to GET INVOLVED! Show you care about the issues that effect you by VOTING! The people who you, the students, put into office this year will represent you not only in the Portland State community but in the entire state of Oregon as well. Get out and vote to make a difference!

**Vote Bazzell/Glock on April 14 &15**

*Get involved and Make a Difference!*

# TELEMEDICINE REPORT TO CONGRESS

January 31, 1997

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## INTRODUCTION

### A. OVERVIEW

As part of the sweeping Telecommunications Reform Act of 1996 (P.L. 104-104), Congress asked the Secretary of Commerce, in consultation with the Secretary of Health and Human Services and other appropriate departments and agencies, to submit a report on the use of advanced telecommunications services for health care purposes. Specifically, the legislation required a summary of the activities of the Joint Working Group on Telemedicine (JWGT)--a Federal interagency working group--as well as findings from Federally-funded telemedicine studies and demonstrations. In addition, Congress requested that the report examine questions related to patient safety, the efficacy and quality of services provided and other legal, medical, and economic issues.<sup>(1)</sup>

Telemedicine has the potential to make a difference in the lives of many Americans. In remote rural areas, where a patient and the closest health professional can be hundreds of miles apart, telemedicine can mean access to health care where little had been available before. In emergency cases, this access can mean the difference between life and death. In particular, in those cases where fast medical response time and specialty care are needed, telemedicine availability can be critical. For example, a specialist at a North Carolina University Hospital was able to diagnose a rural patient's hairline spinal fracture at a distance, using telemedicine video imaging. The patient's life was saved because treatment was done on-site without physically transporting the patient to the specialist who was located a great distance away.

Telemedicine also has the potential to improve the delivery of health care in America by bringing a wider range of services such as radiology, mental health services and dermatology to underserved communities and individuals in both urban and rural areas. In addition, telemedicine can help attract and retain health professionals in rural areas by providing ongoing training and collaboration with other health professionals.

Before launching into a full discussion of telemedicine and its related topics, it is important to clarify the definition and scope of telemedicine. For the purposes of this report, "telemedicine" refers to the use of electronic communication and information technologies to provide or support clinical care at a distance. Various broader definitions of "telemedicine" have been previously proposed, such as the Institute of Medicine's<sup>(2)</sup> interpretation in its recent publication on telemedicine.

More broadly speaking, the term "telehealth" is often used to refer to a diverse group of health-related activities, such as health professionals' education, community health education, public health, research, and administration of health services. Although this report primarily focuses on telemedicine, it should be noted that almost all of the telemedicine activities funded by the Federal agencies have some broader telehealth applications. Moreover, the JWGT is particularly interested in broadening its activities to telehealth over the coming year.

Telemedicine, as we define it here, is still in its developmental phase. It has been estimated that more than 60 percent of the current non-radiology telemedicine projects have been established in the last three years, mostly with the investment of Federal dollars.<sup>(3)</sup> The projects and networks now operating are just beginning to test the potential of telemedicine to deliver health care services, safely and efficiently. What is known today about telemedicine represents only an initial snapshot of a technology that is changing and expanding daily. Given that telemedicine is still in its early stages, the report's scope is limited to a current status report of federally-funded telemedicine studies and projects.

Chapter I discusses the Joint Working Group's membership, structure, and scope of activities; Chapter II outlines the Joint Working Group's work on project evaluation, individual agency participation in telemedicine projects, and lessons learned from the projects. The remaining chapters highlight issues that must be resolved if telemedicine is to proliferate. Chapter III looks at important legal issues such as interstate licensure and malpractice; Chapter IV discusses payment for telemedicine services. In Chapter V, we examine factors related to the safety of telemedicine, including the development of standards. Chapter VI provides an overview of how telecommunications infrastructure costs as well as the implementation of telecommunication reform may affect telemedicine. The last chapters briefly touch upon privacy, confidentiality and security, which, for the most part, are being discussed on a more general level throughout the Federal government. We then summarize future steps for the Joint Working Group for the next year.

## **B. HISTORY AND CHARGE GIVEN TO THE JWGT**

Given the significant potential benefits that telemedicine may offer, Vice President Gore identified telemedicine as a key area requiring attention to ensure progress in the development of the NII. Since 1992, the Information Infrastructure Task Force (IITF), under the leadership of the Department of Commerce, has examined broad innovative uses of the NII and has coordinated NII initiatives throughout the Federal government. It created the Health Information Application Working Group in early 1994 with a subgroup that focused upon telemedicine.

In March 1995, the Vice President asked the Department of Health and Human Services (HHS) to take more of a leadership role in developing Federal policies to foster cost-effective health applications for the National Information Infrastructure (NII). Subsequently, the IITF's working group joined forces with HHS to form the Joint Working Group on Telemedicine, which is chaired by the acting director of the Office of Rural Health Policy, Health Resources and Services Administration (ORHP).

Today, the Joint Working Group is a government-wide entity that has grown to more than eight member departments and agencies. The JWGT is charged with assessing the role of the Federal government in telemedicine and coordinating telemedicine activities across Federal cabinet agencies. Part of that task involves developing specific actions to overcome barriers to the effective use of telemedicine technologies.

## **C. STRUCTURE OF THE JWGT**

The Joint Working Group is made up of representatives from Federal departments and agencies that have a substantial interest in telemedicine. A current list of participants is attached in Appendix A.

JWGT members are involved in several different aspects of telemedicine, each member agency bringing unique expertise to the table. Some JWGT member agencies oversee telemedicine grant programs, such as those of the Department of Commerce's National Telecommunications and Information Administration (NTIA), the Department of Health and Human Services' (HHS) Office of Rural Health Policy, Health Resources and Services Administration (ORHP), the National Library of Medicine (NLM), Agency for Health Care Policy and Research (AHCPR), the Department of Agriculture's Rural Utility Service (RUS), and the Appalachian Regional Commission (ARC).

Others are critical players in the regulation or financing of health care or telecommunications services, such as the Food and Drug Administration (FDA), the Federal Communications Commission (FCC), or the Health Care Financing Administration (HCFA). Some other members, such as National Aeronautics and Space Administration (NASA), the Department of Veterans Affairs (VA), the Indian Health Service

**Box 1: Federal Agency Telemedicine Focus**

**The U.S. Department of Agriculture's (DOA) Rural Utilities Service's (RUS) Distance Learning and Telemedicine Grant Program** provides telecommunication grants to help in infrastructure development for improving rural health care and education.

**The Appalachian Regional Commission (ARC)** funds telecommunication initiatives that benefit multiple community players within the 13-state Appalachian region stretching from Mississippi to New York.

**The Department of Commerce's (DOC) National Telecommunications and Information Administration (NTIA)** through the TIIAP Program provides grants for innovative model projects using the National Information Infrastructure in health, education and other social services.

**The Department of Defense (DoD)** uses telemedicine technology to provide direct health care delivery to its beneficiary population through a large network of tertiary facilities and also is involved in the rapid prototyping of telemedicine applications for battlefield conditions.

**The Department of Justice (DOJ)** funds demonstration projects to examine the benefit of using telecommunications to provide safe and effective access to care for its inmate population and avoid costly patient transfers.

**Department of Health and Human Services (HHS)**

**The Agency for Health Care Policy and Research (AHCPR)** provides support for the rigorous evaluation of health system innovations, including the application of telemedicine systems to assess clinical effectiveness and patient satisfaction.

**The Health Care Financing Administration (HCFA)** funds telecommunication projects to test the effects of telemedicine services on access to care, patient and provider satisfaction, and quality and cost of services to the Medicare program.

**The Indian Health Service (IHS)** uses telemedicine technology such as teleradiology to help serve its native American population in medically underserved areas.

**The National Library of Medicine (NLM)** telemedicine program evaluates the impact of the National Information Infrastructure (NII) on health care, medical research, and public health.

**The Office of Rural Health Policy, Health Resources and Services Administration (ORHP)** funds projects to demonstrate and evaluate the effectiveness of telemedicine programs in improving access to health services for rural underserved communities. ORHP has been at the forefront of developing tools for evaluating telemedicine programs across a wide range of projects.

**The National Aeronautics and Space Administration (NASA)** has been a pioneer in the development and application of telemedicine for more than 37 years. NASA has utilized domestic and international telemedicine testbeds to evaluate and enhance health care delivery procedures and protocols for remote locations.

**The Department of Veteran Affairs (VA)** implements and tests telemedicine solutions that utilize a wide-area network to provide health care services to its beneficiaries across the country. The agency's system also tries to merge data obtained from commercial telemedicine products with VA-developed hospital information

(IHS), the Department of Justice (DOJ), and the Department of Defense (DoD), use telemedicine for direct health care service delivery or conduct basic research and development on telemedicine. The Office of Management and Budget (OMB) provides oversight. Box 1 provides a brief overview of each agency's telemedicine focus.

The JWGT meets approximately twice a month. These

meetings provide an opportunity for information exchange, agenda setting, and decision making. The actual work of the JWGT is conducted primarily in smaller subgroups that are formed to address specific issues (e.g., telemedicine evaluation). Subgroups meet as needed.

Increasingly, the Federal government's telemedicine activities involve a partnership with the private sector to achieve its objectives. The Working Group is committed to hearing from experts from the private sector throughout its deliberations to gain the widest range of expertise possible. The JWGT meetings have featured presentations on emerging telemedicine issues from the Council on Competitiveness, the Center for Public Service Communications, Federation of State Medical Licensing Boards, the American Medical Association, the Institute of Medicine, the American Telemedicine

Association, the Council of the State Boards of Nursing, and Abt Associates, which conducted the first national survey of rural telemedicine projects.

## D. WORK PLAN OF THE JWGT

At its inception in 1995, the diverse membership of the JWGT brought different levels of telemedicine expertise to the table. The committee has worked to educate its members through both distributed material and presentations at meetings from both public and private sector groups that specialize in this field. These efforts helped the group achieve greater consensus on a range of key issues.

Early on, the JWGT developed an 18-month work plan that included consultation with constituency groups and review of policy papers. Some of these papers were written by representatives of the Department of Health and Human Services. Others were produced by groups such as the Western Governors' Association and the Council on Competitiveness. The committee also reviewed summary reports from the major telemedicine seminars, forums, and conferences held over the past four years. Over time, a number of issues began to emerge. From there, the JWGT began working on the following issues, organized by chapter.

### I. Introduction and History of the Joint Working Group.

**II. Development of a Working Inventory of Federal Projects.** In his memo to Secretary Shalala, Vice President Gore directed the Department to report on current telemedicine projects funded by the Federal government. As the group soon discovered, there was no comprehensive inventory available. The JWGT therefore identified the development of a Federal inventory as a high priority activity.

**Evaluation.** Although many individuals believe strongly in the potential of telemedicine for providing cost-effective services, not much hard data is available to support that belief. Decision makers want to know the value-added of telemedicine. Lack of solid evaluative information is a significant barrier to the deployment of telemedicine.

**III. Legal Issues/ Licensure.** Telemedicine has the potential to overcome barriers of distance in providing health care. State professional licensure laws, however, are perceived as posing a significant obstacle to achieving this potential in health care markets that cross state boundaries.

**IV. Third Party Payment Policies.** Private third party payers, including managed care plans, have been reluctant to pay for telemedicine services. And federally-funded programs such as Medicare and Medicaid provide limited coverage. Without adequate reimbursement payments, the long term survival of telemedicine is in question. Thus, understanding the barriers to third party payment and how to overcome them has been a high priority for the JWGT.

**V. Safety Standards.** The Federal government's, and particularly the FDA's, role in protecting the public against unsafe and ineffective telemedicine products was an issue identified early in the deliberations of the JWGT.

**VI. Telecommunications Infrastructure.** The unavailability and high cost of telecommunications services in rural and some urban communities has been a major barrier to telemedicine. Reducing these costs and improving access is critical if sustainable telemedicine systems are to be available in rural and other under-served communities.

**VII. Privacy, Security and Confidentiality.** Concerns about protecting personally identifiable information are not limited to the telemedicine arena. Thus, several Federal Agencies are already examining general privacy, security and confidentiality issues related to the NII. Yet, there are privacy issues that are unique to telemedicine. For example, when a two-way video system is used in a clinical consultation, the patient and health professional may be joined by a technician and camera person. This increase in the number of people involved in a particularly sensitive consultation such as the provision of behavioral health care, could pose new challenges to privacy concerns. It is also difficult for the patient to know who else may be viewing the consultation.

These issues and the activities undertaken by the JWGT to address them will be discussed in greater detail in the following chapters.

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## FOOTNOTES

1. S. 652. 104th Cong., 1st Sess. (1996) *Telecommunications Reform Act* (Section 709)
2. Institute of Medicine, "Telemedicine: A Guide To Assessing Telecommunications in Health Care", 1996.
3. Office of Rural Health Policy/Abt Associates Study.

# TELEMEDICINE REPORT TO CONGRESS

January 31, 1997

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## EVALUATION

### A. OVERVIEW

The advance of telemedicine technology has created a host of relevant new clinical and educational applications. From video conferencing to store-and-forward capability, health care professionals are finding many uses for this technology. The next challenge lies in answering critical technical, clinical, and organizational questions about what works and what does not.

The need for more evaluation of this technology has been a pressing concern for the Joint Working Group on Telemedicine. A recent report from the Institute of Medicine (IOM) and a soon-to-be released General Accounting Office (GAO) report have stressed the importance of the JWGT as a structure for coordinating Federal programs and, more specifically, creating a process of sharing evaluative information across agencies.

This chapter will provide an overview of collaborative and individual efforts of the JWGT-participating agencies. These activities include the Federal Telemedicine Gateway, the Joint Evaluation Framework, the Institute of Medicine report, and the Office of Rural Health Policy/Abt survey of rural telemedicine. The chapter will also outline what is known about the use of telemedicine and provide a list of lessons learned from the various Federal projects and initiatives.

### B. THE FEDERAL TELEMEDICINE GATEWAY AND INVENTORY OF HEALTHCARE DELIVERY PROJECTS

Despite the growing interest in telemedicine, and the need for "hard data," little is currently known about the extent of telemedicine in the United States. To address this need for more information, the JWGT is examining the use of World Wide Web technologies to create an inventory of Federal telemedicine activities. The intent of this initiative is to simplify the collection of and timely access to data on Federal telemedicine activities. The development of software and procedures to ease maintenance of data and ensure security and privacy is currently underway. These developments will enable individual agencies to maintain and update their own project information in a quick and cost-effective manner.

Using a Department of Defense contractor and technical assistance from the Departments of Defense (DoD), Health and Human Services (HHS), Veterans Affairs (VA), Agriculture (USDA), and the National Aeronautics and Space Administration (NASA), the JWGT created an inventory and data base that eventually will be available to the public on a web site. The Federal Telemedicine Gateway web site includes an inventory of federally-funded projects as well as linkages to other web sites that contain information on telemedicine activities in the private sector and states.

The inventory includes information from demonstration grant projects from the Department of Commerce, the Department of Health and Human Services, the Appalachian Regional Commission and the Department of Agriculture. It also includes direct provision of health care services through the Indian Health Service, the National Aeronautics and Space Administration, the Department of Defense, the Department of Veterans Affairs, and the Department of Justice.

At the most fundamental level, the inventory contains a data base that includes basic descriptive information on each Federal project, including names of individuals to be contacted for further information. Wherever possible, available information is organized in a uniform format, allowing analyses across projects. The data base is incorporated into a geographic information system that

facilitates linkage of information in the inventory to other basic data about communities in which telemedicine projects are implemented. Basic analytic reports are to be developed from the information maintained in the inventory.

### C. SUMMARY OF THE GATEWAY AND INVENTORY

The inventory and Gateway can and should be viewed as a prototype. In particular, once developed, additional data, such as those on distance learning or public health applications of telecommunications, can be added to the inventory. Several states have expressed interest in being linked to the inventory once it is developed. Moreover, the basic design of the inventory could be very useful to other initiatives that need to be tracked by the Federal government, e.g., Medicaid or welfare reform demonstrations.

Currently, the inventory is undergoing technical evaluation. Initial evaluation has revealed some of the limitations of the web technology available today. It also has shown the weaknesses in the information reported and maintained by Federal agencies, highlighting the need for greater attention to routine data collection on federally-funded programs. Release of the complete inventory is anticipated by the end of February 1997, assuming that all technical problems can be addressed by the contractor by mid-January.

Access to the Gateway is currently available through the World Wide Web (WWW), with levels of access assigned according to organizational affiliation and project participation. Access to the database is available at <http://www.tmgateway.org>.

### D. THE FEDERAL EVALUATION FRAMEWORK

The absence of evaluative information continues to be a hurdle to a wider use of telemedicine. Policy makers at both the Federal and state levels may find it hard to answer critical questions regarding cost, infrastructure, quality, and effectiveness without more sound and thorough information about the use of telemedicine to improve health care delivery. However, there are efforts underway to address these concerns. To facilitate coordination among Federal agencies and with the states and private sector, the JWGT has developed a framework<sup>(1)</sup> for evaluating telemedicine projects. The framework (outlined in Box 2 ) represents a blueprint for sharing information across federally-funded projects and studies. It provides examples of the questions that need to be asked dfor six major areas or domains of concern. These questions are generic and could apply equally to Federal and non-Federal projects and studies.If

**Box 2: The Federal Evaluation Framework**

Telemedicine evaluation should be designed to address questions in at least six areas or domains:

- Clinical Outcomes.** Are acceptable outcomes associated with the use of telemedicine?
- Technical Acceptability.** Is the system technically acceptable?
- Health Systems Interface.** How well is the system integrated into the overall health system?
- Costs and Benefits.** What are the costs and benefits of such a system in day-to-day operations? Is the system affordable?
- Patient/Provider Acceptability.** Will patients and providers accept and value telemedicine-enabled care?
- Access.** Will the use of telemedicine improve access to health care?

The domains are not mutually exclusive, because factors that affect one domain may also have a profound effect on another.

successful the framework also should facilitate cooperati evaluatio efforts with private-se telemedic projects.

### E. OTH EVA ACTI

### BY JWGT AGENCIES

ORHP has funded a cooperative agreement with the Telemedicine Research Center to develop uniform data collection instruments and collect uniform evaluation data in the 20 networks funded by ORHP. HCFA is funding an evaluation of health systems utilization and cost-effectiveness with telemedicine. The two agencies also are pursuing development of common evaluation instruments. If successful, these instruments would allow for comparison of information across the two agencies, thus increasing the amount of data available and strengthening each agency's ongoing evaluation efforts.

At the Department of Commerce, NTIA's Telecommunications and Information Infrastructure Assistance Program requires each of its grantees to conduct evaluations of their telemedicine projects. In addition, NTIA recently released *Lessons Learned from the Telecommunications and Information Infrastructure Assistance Program*, a report based on the experiences of its grantees with a variety of information infrastructure projects in health, education, and other social services.

The Department of Defense has embarked on a comprehensive evaluation of telemedicine within some of its demonstration projects and the use of telemedicine in support of deployed troops (e.g., in Bosnia, Haiti, and Somalia). The DoD evaluations include the development of outcomes measures to assess the clinical efficacy of telemedicine. The NLM has funded contracts to evaluate the information content necessary to make good clinical decisions using various telemedicine technologies. The Agency for Health Care, Policy & Research (AHCPR) has awarded one grant and may award additional grants to examine the cost and medical effectiveness of telemedicine. The results of these studies, and others, will help answer critical questions about what works and what does not in telemedicine.

## **F. THE INSTITUTE OF MEDICINE REPORT ON TELEMEDICINE EVALUATION**

The Institute of Medicine (IOM) report, funded by the NLM and other Federal agencies, provides one of the more comprehensive assessments of telemedicine evaluation to date. This report provides further refinement of the JWGT framework and outlines many of the next steps to be taken in evaluation as shown in Box 3. The IOM's committee evaluation framework includes four components: principles, planning processes, evaluation elements, and evaluation questions. These principles call for the evaluation to be:

- Incorporated from the start of project planning;
- Viewed as a cumulative process of building knowledge, not as an isolated effort;
- Organized around comparisons with the benefits and costs of relevant health care alternatives;
- Aimed at identifying practical, affordable, and sustainable applications

### Box 3: Institute of Medicine: Evaluation Elements for Clinical Telemedicine

#### Project description and research questions.

**Strategic objectives.** How the project is intended to serve the sponsor's purposes

**Clinical objectives.** The effects the program is intended to have on the quality, accessibility, or cost of care

**Business or project management plan.** How the evaluation will help decision makers judge whether and when the application will be financially and otherwise sustainable, or, less formally, a description of the project's management, work plan, schedule and budget.

**Level and perspective of evaluation.** Whether the viewpoint of the evaluation is clinical, institutional, or societal.

**Research design and analysis plan.** The steps for developing valid comparative data.

- **Experimental and comparison groups:** *the characteristics of the group(s) that will be involved in testing the target telemedicine application and the group(s) that will receive conventional or alternative services*
- **Technical, clinical, and administrative processes:** *as planned and as actually implemented, the communications and information systems, patient care practices, and supportive organizational procedures*
- **Measurable outcomes:** *the data to be used to determine whether a project is meeting its clinical and strategic objectives*
- **Sensitivity Analysis:** *the use of techniques to assess the extent to which conclusions might change if assumptions or values of key variables changed*
- **Documentation:** *the explicit reporting of the evaluation methods and findings so that others can determine how conclusions were established*

## G. THE OFFICE OF RURAL HEALTH POLICY/ABT SURVEY OF RURAL TELEMEDICINE

In January, 1997, ORHP released the first major national survey of rural telemedicine. "The Exploratory Evaluation of Rural Applications of Telemedicine", conducted by Abt Associates, Inc., which includes information about the extent to which telemedicine is used in rural areas, by whom, for what purposes, and the costs.

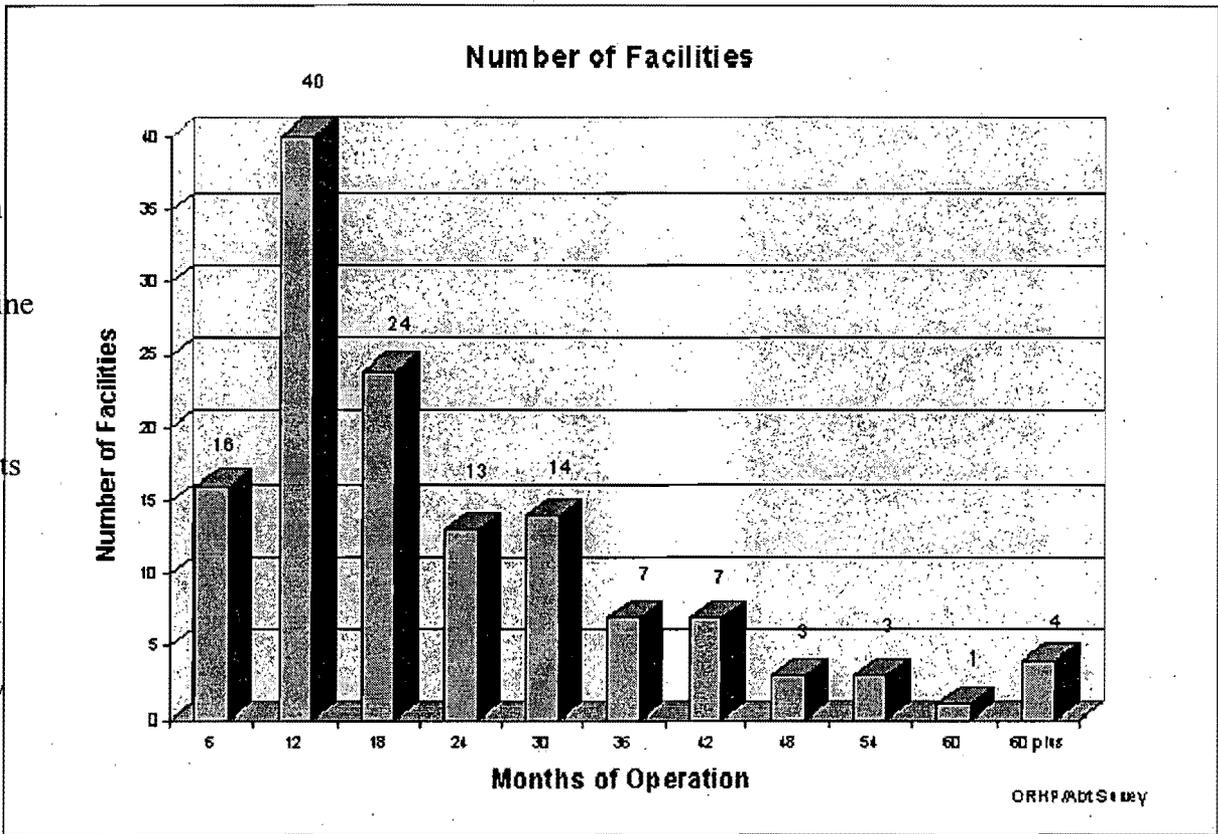
### Key Findings

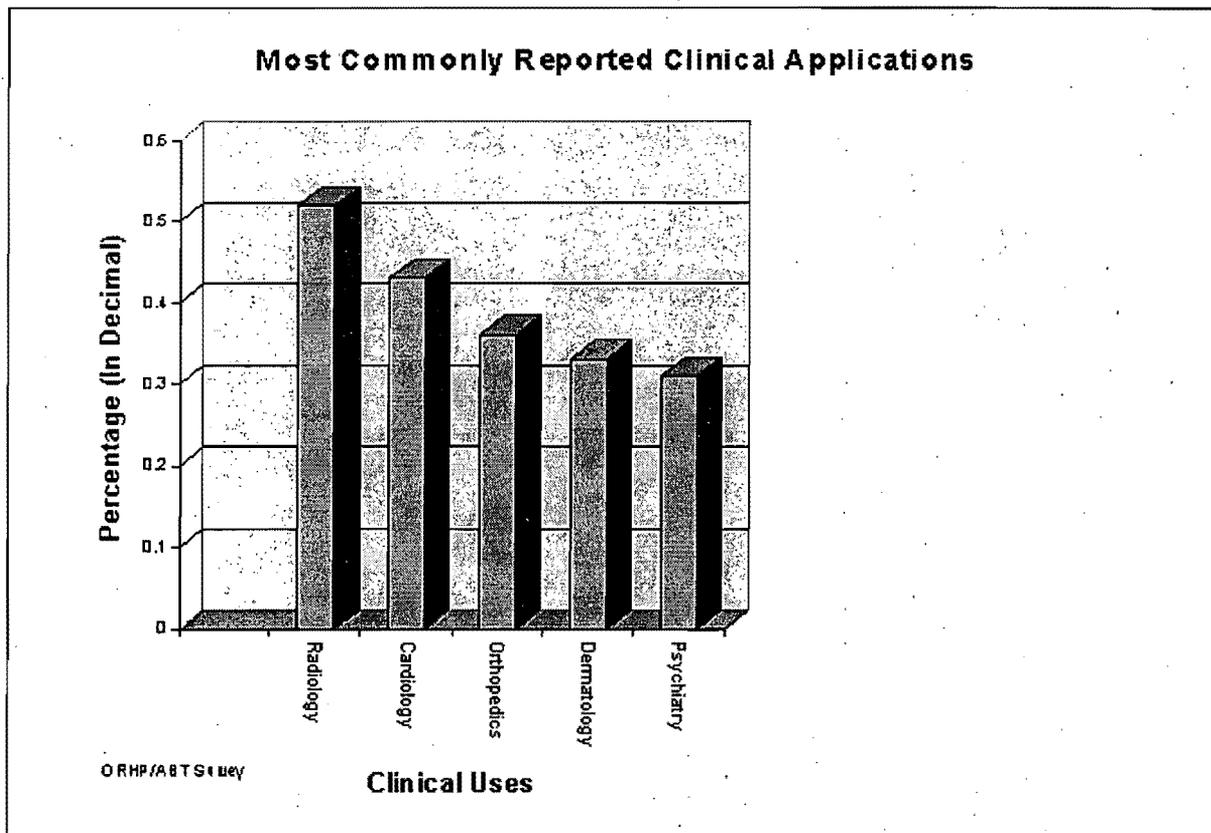
By the beginning of 1997, nearly 30% of the 159 rural hospitals surveyed in the winter of 1996 are expected to be using some sort of telemedicine technology to deliver patient care. Of these, 68% are expected to offer only teleradiology.

More than 40% of the telemedicine programs surveyed had been providing teleconsults for one year or less.

Radiology and cardiology were the most common clinical applications reported, followed by orthopedics, dermatology and psychiatry.

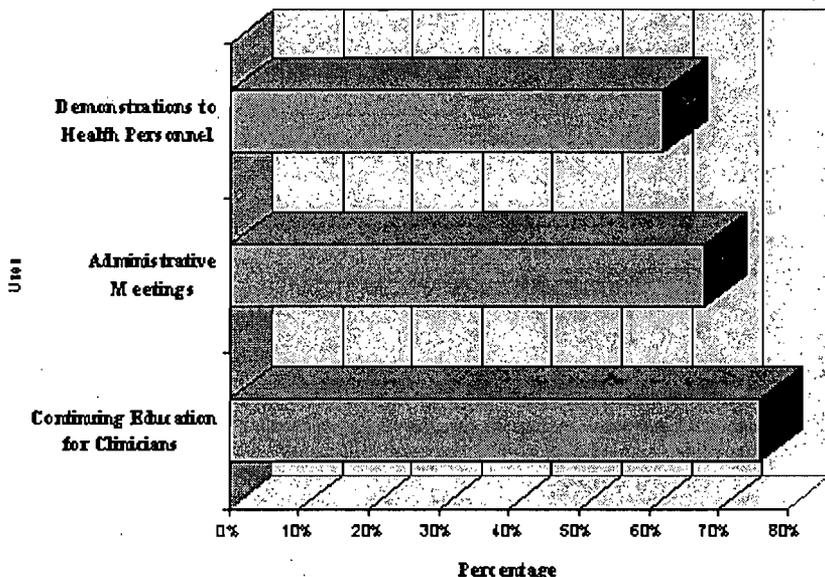
Telemedicine systems were also used for non-clinical applications such as continuing education for health professionals. Fifty-eight percent of the sample had used their equipment for four or more different non-clinical uses.





Despite growth and expansion, the cost of telemedicine remained high. The average equipment purchase, excluding switches and new lines ranged from \$134,378 for "spoke" sites to \$287,503 for "hub" sites.<sup>(3)</sup> Reported annual transmission costs were also high, ranging from an average of \$18,573 for spokes to \$80,068 for hubs. Slightly less than 20 percent spent less than \$50 per session in transmission costs, while seven percent spent at least \$500 per session. High costs, combined with low utilization in the early years of operation, yielded high unit costs. A teleconsult cost the median or typical hub site \$1,181, while the median spoke site spent \$476 per consult, exclusive of any reimbursement to clinicians.

### Non-Clinical Applications



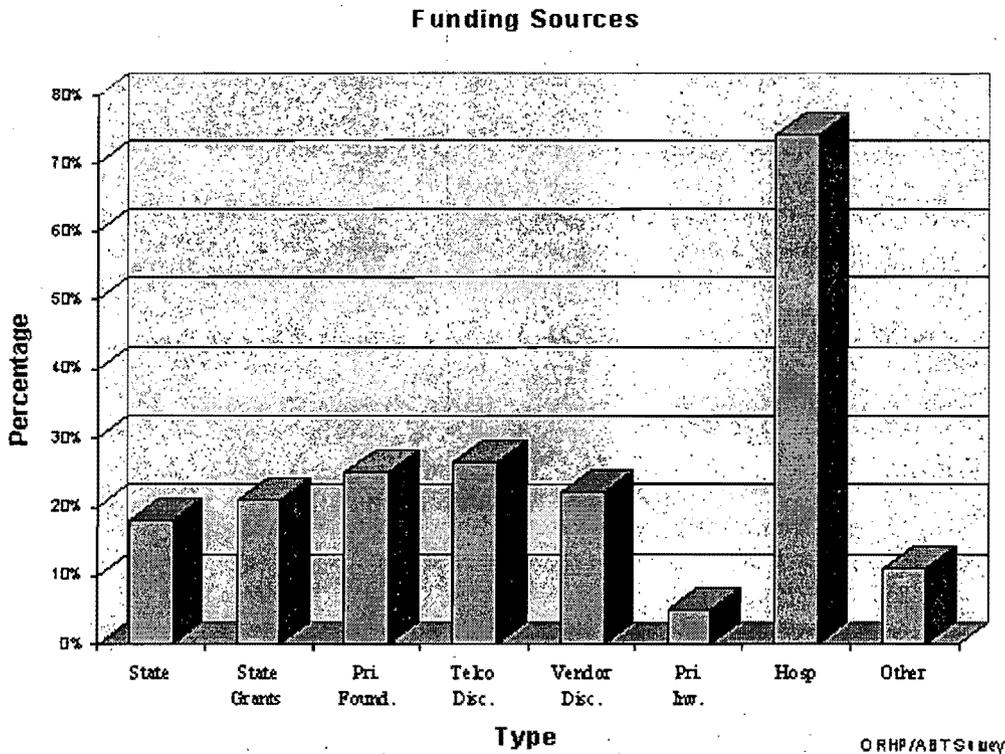
ORHP/ABTS:uey

Federal and state grants were common sources of direct funding for telemedic programs, and the majority of sites also received hospital financial support. Third-party reimbursement for telemedic was elusive; fewer

than 25% of hub facilities had successfully negotiated payment with insurance carriers and many had not yet undertaken such negotiations.

The most common transmission technologies involved copper telephone lines (78 percent of Telemedicine facilities and 83 percent of Teleradiology Only facilities), and dedicated telecommunication services such as T1 (76 and 29 percent of Telemedicine and Teleradiology Only facilities respectively). Fiber optic lines were also commonly reported (52 percent of Telemedicine facilities) as were switched services such as switched 56 Kbps and ISDN. Satellite or microwave

transmission were each mentioned by less than 10 percent of respondents. Thirty eight percent of responding sites reported availability of not only a dedicated service, but also a switched service.



The majority of telemedicine

facilities reported the use of real time technologies for the transmission of data and images (90 percent). Two-thirds had store-and-forward technologies available, and most had both.

Utilization was low in the first years of most rural telemedicine programs. Only 17 percent used their system more than once each day.

Sixty percent of facilities that had been operating between one and two years had a narrow range of clinical applications whereas those operating for two or more years were more likely to have a broader set of applications (62 percent).

## H. LESSONS LEARNED

In addition to the information provided by the IOM and ORHP/Abt studies concerning telemedicine trends, there have been important lessons learned on a project by project basis from the experience of federally-funded telemedicine projects.

The majority of federally-funded telemedicine projects are currently in the early stages of development. Most have been in existence for only three years or less. Thus, similar to any startup company, these projects have faced steep learning curves. Despite this relatively short history, project developers have gleaned some early lessons from the pre-planning, startup, and sustainable phases of the telemedicine projects' development.

### Pre-planning Phase

Pre-planning is probably the most important phase in the development of a telemedicine system. In this phase, the telemedicine planners must identify their client's needs, the scope of their market, the type of technology that fits the market, and the type of infrastructure that will meet their needs.

**Develop a business plan.** Among Federal grantees, those organizations that developed a solid business plan were more successful than those that did not. In the business plan, it is important to anticipate and plan for sustainable service once subsidies are gone. In addition, a business plan should include:

**A thorough needs assessment.** Find out about the community's clinical and educational needs. Canvass users from the beginning. User input is critical to the success of the project, helping to avoid mismatches between equipment and needs. Early user input is critical not only in determining the type of technology used but also in the design of the system.

#### Box 4: Assessing Client Needs

The University of Cincinnati Medical Center Library conducted focus groups with community residents before developing its NTIA-supported NetWellness project. NetWellness provides electronic access to information on health topics such as aging, breast cancer, diabetes, and nutrition, and offers an E-mail-based Ask-the-Expert@ service. Through the initial focus group sessions, the project team was able to identify the health topics of greatest interest to the local community and then tailor their information service around those topics.

**Technology matched to clinical needs.** Clinical needs, not technology, should drive the development of a telemedicine system. Successful projects used a thorough technology assessment to select the most simple and least expensive equipment to meet their clinical requirements.

**A clear understanding of the existing telecom delivery system.** The goals and objectives within that delivery system need to be understood and incorporated into the system and organizational design. System designers must begin with a careful analysis of the present telecommunications infrastructure and build upon it. They must consider modes of transmission, such as copper, fiber optics, satellite, and cable. Types of technology such as PC-based vs. dedicated teleconference systems stems must be evaluated in terms of the benefits vs. cost.

**Flexibility.** The rapidly changing nature of telemedicine technology puts a premium on creating flexible systems that can adapt to new equipment. Designers of telemedicine delivery must constantly strive to develop systems that are readily adaptable to improvements in technology as well as reductions in cost. To the extent possible they should incorporate off-the-shelf equipment that does not require a great deal of customizing. Customizing can be expensive and may demand greater technical expertise in geographic areas where such expertise is not readily available.

**Simplicity--"Keep it simple".** This is a principle familiar to those serving in the armed services (See Box 5). The choices in telecommunications and computer based technology, coupled with the variety of medical applications possible,

#### Box 5: Mental Health Care

Unlike some specialties such as cardiology, mental health telemedicine applications do not require a high degree of image specificity, thus the technology can be simpler and costs can be lower. Moreover, initial evidence indicates that telemedicine works well for group therapy as well as individual consults.

As noted in the OHRP/Abt Report, Mental Health Care ranked among the top five telemedicine applications in terms of usage.

creates an overwhelming array of options when developing telemedicine systems. Experience leads us to believe that the most successful systems are those that use the simplest and least expensive technology to meet a need.

**Human factors.** The design of any telemedicine system must be viewed as useful to the practitioners. Physicians and other health care professionals have difficulty adapting to technology that does not meet their needs. The technology must fit within the scope of practice.

**Negotiating telecommunication costs.** Successful projects quickly learned to negotiate and work with telecommunications vendors and telephone companies to keep transmission costs low. This was particularly important in rural areas, where the telecommunications infrastructure and resulting rate structure vary greatly. In some areas, telephone lines may have to be installed or connected before they will support telemedicine.

Get a price for transmission costs as early as possible, negotiate lower rates, or consider using a lower

bandwidth telemedicine system if it provides adequate resolution and transmission speed. Be as creative as possible in structuring line connections to cross as few Local Access and Transport Area (LATA)<sup>(4)</sup> boundaries in order to keep transmission costs down. Work with the State Public Utility Commission to get the lowest possible rates.

## Startup Phase

### Identify and support a champion.

Effective leadership is the cornerstone of any telemedicine system (See Box 6). Those

#### Box 6: The Value of a Champion

In Fort Stockton, Texas, the Office of Rural Health Policy's MedNet project was supported by an able administrator but not by the clinician community, which already had well-established referral relationships with specialty physicians whose practices were within reasonable travel time for patients. As a result, telemedicine never got off the ground. In contrast, in Alpine, Texas, distances to specialty services were greater, and from the beginning at least one physician championed the project.

projects that supported a champion were more likely to be successful than those that did not. It was also important to target leaders from within the community's power structure who were able to dictate action and commit resources--both financial and human. Minimally, there should be clinical leadership because it is practitioners who drive telemedicine use.

**Communicate a common vision.** As in any successful business, a common vision of goals, priorities and needs must be communicated to all levels of the team--from the leaders to the practitioners to the technical support.

**Start evaluation right away.** It is important to collect data right away. This will be valuable in your negotiations with insurers for reimbursement. They will base any decision on data relating to quality, access, and costs.

### Foster multiple uses.

Successful networks do more than just clinical consultations. In the early

#### Box 7: Foster Multiple Uses

The Hays, Kansas rural health office is part of a telemedicine network funded by the Rural Utilities Service. Network partners use the equipment not only for medical consultations but also for health education, continuing medical education and administrative meetings. "Small communities that can tap into this are really going to thrive," Bob Cox—a pediatrician—told Rural Electrification Magazine. "The application of telemedicine is really going to explode."

stages, the clinical consult figures tend to be very low. Without multiple uses, it is hard for a network to become self-sustaining, quickly. Making the network available to other groups for administrative meetings, continuing education, degree programs, grand rounds, and community meetings can help lead to long-term viability. (See Box 7)

## Sustainable Phase.

**Maintain training and on-going technical assistance.** Securing a good source of technical assistance is important from the "get go" of the project. Often, the only readily available source of technical advice may be vendors. Thus, network participants must develop a critical mass of technical expertise at both the receiving and sending sites. This responsibility cannot be vested in one individual per location, but rather enough to cover all the hours that the network is utilized. Training on this equipment should also be extended to the health professions so that providers will be familiar and comfortable with this

technology as they move from training to practice.

**Standards and protocols should work together:** In order for the various telemedicine

equipment and software to work together, standards and protocols must be established and must work together. Standards have been critical to the success of Columbia Presbyterian Medical Center's tuberculosis project (see Box 9). Information exchange, privacy and security were all dependent upon

the existence of consistent standards among the participants. For example, the three organizations had to map data elements from one organization

to the other. By choosing the Health Level 7 standard as the data messaging standard and TCP/IP as the data transmission standard, this process was helped greatly. Moreover the Center found that "without some kind of agreement or standard policy, privacy and security levels may differ greatly and preclude necessary information and data exchange."<sup>(5)</sup> The center also attributed its success to the fact that this project was designed from the bottom up. Thus, the people facing a particular problem came up with solutions to the problem and were committed to the success of the project. The champions were close to the problem and they created a solution that was tightly focused.

## I. NEXT STEPS

Detailed studies, separate from the demonstrations, are underway to begin to collect better clinical and cost data from the various agency demonstrations. Results from these studies, however, will take time. Current projects are just beginning to emerge from the proof of concept stage and it will take time to gather a critical volume of experience and data to answer many of the questions posed regarding telemedicine. For this reason, the agencies have been interested in developing common data collection tools that will permit aggregation of data across projects, whenever possible. Some of the next steps for evaluation include:

**Uniform Evaluation Tool Development.** As noted above, ORHP has awarded a grant to the Telemedicine Research Center to develop and evaluate instruments for creating a common data set for application across all agencies. Emphasis will be on collecting common data elements on clinical encounters, costs, and the structure of telemedicine provider organizations, whenever possible. The instruments will be first used in ORHP's 20 demonstration projects. The ORHP efforts will be closely coordinated with those of NLM and HCFA, the latter has awarded a major contract for an evaluation of telemedicine specifically focused on information required to develop payment policies. (See the discussion on HCFA payment demonstration.)

NTIA and the Rural Utilities Service are also coordinating their evaluation efforts with other agencies through the JWGT. It is hoped that this effort will result in data collection tools that would allow for analyses of data across projects.

### Box 8: Importance of Training and Support

The importance of training and support is underscored by the preliminary evaluation study of the NC Telemed project funded by NTIA. According to the study, a number of participants did not feel adequately prepared for the demonstration project, indicating that they did not have sufficient information about the project purpose, their specific responsibilities, or the procedural changes that the project would necessitate. However, those that did receive training noted that the training reduced the concerns they had about using the technology and provided them with the necessary skills to operate the telemedicine equipment.

### Box 9: Working Together—Using Standards

Standards played a critical role in the Columbia Presbyterian project which deals with the highly infectious disease, tuberculosis. Columbia University, the New York City Department of Health and Visiting Nursing Service are finding that telemedicine with appropriate standards can play a key role in protecting public health. This award winning project funded by NTIA, uses modern telecommunications technology to link the three agencies, share case reports, notify each other of new cases, and track TB patients. Visiting nurses also use wireless communication to access and update hospital records as they make their rounds.

**Evaluation of Medicaid Telemedicine Programs.** Currently, 10 states offer some telemedicine coverage under their Medicaid programs, but there is no general evaluation effort or opportunity for them to share their experiences, successes, and failures. The JWGT will assess the current level of evaluation activity in the Medicaid program and work with selected states to promote better evaluation. In particular, the JWGT will work with HCFA and ORHP to develop strategies for using state offices of rural health and HCFA regional offices to develop an ongoing mechanism to track Medicaid activities.

**Evaluation of Telemedicine in Managed Care Settings.** Evaluation studies of telemedicine need to be expanded to managed care settings, and in particular, to rural managed care settings. Currently, there is very little penetration of managed care in rural settings, but several managed care plans, most notably in Minnesota and California, believe that telemedicine might provide a more cost-effective way for the plans to reach rural communities with needed services. Questions remain as to whether telemedicine technologies will be beneficial to rural communities in the long run through the provision of specialty care that would otherwise not be available, or will they result in reduced access and availability of care because specialists are no longer visiting these communities to provide care? HCFA is discussing the use of telemedicine with several large Medicare risk-based managed care plans. ORHP has had a number of inquiries from managed care plans that would like to be able to apply for ORHP grants this year to evaluate telemedicine programs.

**Quality and Efficacy of Care.** Very little current research is systematically evaluating quality and efficacy of telemedicine services. This is a very complicated area of research that needs to be pursued over the next two years, if this nation is to be a credible leader in telemedicine. DoD and the Agency for Health Care Policy and Research (AHCPR) are working together to develop strategies for assessing the clinical efficacy of telemedicine for specific specialty applications. This work may serve as a foundation for other agencies to build upon. State-funded initiatives are also beginning to establish research and demonstration efforts to assess the clinical efficacy of telemedicine services provided in different specialties. The JWGT plans to actively broker partnerships between these state and Federal efforts.

**Evaluation of Telemedicine in Post-Acute Care (Home and Long-Term Care) and in Non-Health Care Settings.** Based on phone inquiries from the health care industry, this is clearly a priority area. One study in Ohio suggests that over 30 percent of emergency hospital readmissions of Medicaid patients from nursing homes might be prevented by timely teleconsulting triage with the patient's primary care practitioners. The JWGT will work with agencies currently funding projects in post-acute and non-health care settings to develop standard evaluation tools.

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## FOOTNOTES

1. Puskin, D. Brink, L. Mintzer, C. Wasem, C. (1995). Joint Federal Initiative for Creating a Telemedicine Evaluation Framework. *The Telemedicine Journal*. 1 (4).393-397.

2. Ibid.

3. "Hub" facilities are those providing health care services whereas "spoke" facilities are those receiving the services. Typically, a specialist at a hub facility could serve patients at different long distance spoke sites.

4. Local telephone service areas created by the divestiture of AT&T into the seven Regional Bell Operating Companies. Telecommunications crossing LATA borders are typically higher in cost .

5. From the quarterly evaluation of the Columbia Presbyterian Medical Center, NTIA, Department of Commerce, 1995 .

# TELEMEDICINE REPORT TO CONGRESS

January 31, 1997

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## LEGAL ISSUES--LICENSURE AND TELEMEDICINE

### A. OVERVIEW

Telemedicine raises a number of legal concerns regarding licensure and professional accountability, particularly relating to cross-state practice. The purpose of licensing health care professionals is to protect the public from incompetent or impaired practitioners. Although interstate telemedicine is not currently widespread, state licensure laws are perceived as a barrier to the expansion of this type of health care practice in many parts of the country. Recent state action, such as that by Kansas, to tighten current licensure laws in response to telemedicine, have further raised concerns about state licensure.

Congressional interest in the licensure of telemedicine providers has taken the form of requests for information and proposed legislation, but to date no action has been taken. In May 1995, Rep. Ron Wyden (D-OR) offered and withdrew an amendment that would have prohibited states from "directly or indirectly restrict[ing] interstate commerce by prohibiting any licensed physician from conducting a consultation with a licensed provider in another state using any advanced telecommunications service. . . ." <sup>(1)</sup> Then Rep. Wyden's action led, in part, to the call for this report. In addition, Senators Kent Conrad (D-ND) and Bob Kerrey (D-NE) introduced a bill directing the Secretary of Health and Human Services to make an annual report to Congress on licensure barriers to telehealth <sup>(2)</sup>. This bill was introduced on the last day of the 1996 Legislative session and no action was taken. The issue may be re-examined when Congress meets again in 1997.

In response to these concerns, the JWGT issued a contract to the Center for Telemedicine Law for a background paper on licensure issues. The group also heard from the American Medical Association, the Federation of State Medical Boards, the National Council of State Boards of Nursing, the American Telemedicine Association, the Institute of Electrical and Electronics Engineers, and representatives from the Mayo Clinic who discussed their views on licensure. In addition, the JWGT issued a call for comments on licensure to the general public through the Federal Register. These comments, along with those of the various associations and individuals who generously shared their time with the JWGT, were invaluable in the formation of this chapter. Public comments in response to the Federal Register request are found in Appendix C.

In this chapter, we will review the structure of the current licensure system in the United States, alternate approaches for addressing cross-state licensure barriers to telemedicine, and specific proposals for alternatives to the current system. The chapter ends with a brief discussion of professional liability in telemedicine and a summary of future directions and next steps to be taken by the JWGT. Because most current activity regarding telemedicine and licensure centers around physicians, this chapter focuses on this group of health professionals. However, much of the discussion is equally applicable to other health care professionals.

### B. THE CURRENT LICENSURE SYSTEM

Currently, each state has established a Medical Practice Act that defines the process and procedures for granting a health professional license, renewing a license, and regulating medical practice within the state.

Historically, interstate physician-to-physician communications have not been subject to licensing

requirements. These communications can take a variety of forms including the mailing of x-rays, clinical histories and pathological and laboratory specimens for evaluation and interpretation, and oral or written inquiries to another out-of-state physician involved in the patient's care or in the form of a specific consultative request to a physician with special expertise. In these interstate communications, the consulted physician or other health professional is regarded either as practicing medicine only in his or her home state or as exempt from licensure under the "consultation exception" in the patient's state.

Until recently, few states had addressed issues concerning out-of-state

**Box 10: California Licensure—Unlike Other States**

California's legislation allows out-of-state physicians to practice within its borders only in actual consultation with a California licensed practitioner and prohibits the out-of-state practitioner from having ultimate authority over the care or primary diagnosis of a patient located within California.

physicians who provide patient health care via electronic communications. Like the state medical practice acts on which they are based, the text of specific telemedicine provisions varies significantly from state to state. In the past several years, Kansas, Nevada, California, Connecticut, Indiana, Oklahoma, South Dakota, Tennessee, and Texas have enacted regulations or legislation governing licensure of out-of-state telemedicine health professionals<sup>(3)</sup>. In virtually all situations, except California, the state has required an out-of-state physician to obtain a full and unrestricted license before consulting directly with patients in the state. Additional states are expected to consider similar measures in the coming year.

Further, in response to inquiries regarding telemedicine, the state medical boards in Arizona, Florida, Iowa, Maine, Massachusetts, Pennsylvania and Virginia have interpreted the state licensure statute to require licensure of most out-of-state telemedicine physicians.<sup>(4)</sup> Mississippi, however, has interpreted its statutes in a manner which allows out-of-state physicians to render diagnoses regarding patients in that state without a second license.<sup>(5)</sup>

## C.LEGAL FOUNDATION FOR THE U.S. LICENSURE SYSTEM: IMPLICATIONS FOR TELEMEDICINE

To understand the legal implications of professional licensure for telemedicine, one must first examine the structure of the current licensure system in terms of authority, standards, enforcement and administration.

### Authority

Licensure authority defines who has the legal responsibility to grant a health professional the permission to practice their profession. The vesting of licensure authority in state, Federal or regional powers raises important constitutional and legal questions beyond the issue of licensure.

### State Authority

Historically, under Article X of the U.S. Constitution, states have the authority to regulate activities that affect the health, safety, and welfare of their citizens including the practice of the healing arts within their borders.

(See Box 11)<sup>(6)</sup>

However, the states' power to regulate

**Box 11: State Authority**

The Supreme Court has recognized that "the States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety, and other valid interests, they have broad power to establish standards for licensing practitioners and regulating the practice of professions."

health care may not be absolute because the Commerce Clause of the Constitution limits states' ability to

erect barriers against interstate trade<sup>(7)</sup> and the practice of health care has been held to be interstate trade for the purposes of antitrust laws.<sup>(8)</sup> Interestingly, the potential conflict between the states' power to regulate health professionals and the prohibition against restraints on interstate commerce has not been addressed by the courts. States may regulate matters of "legitimate local concern" even though interstate commerce may be affected.<sup>(9)</sup>

Even overt discrimination against interstate trade may be justified where out-of-state goods or services are particularly likely to threaten the health and safety of a state's citizens and where outright prohibition, "rather than some intermediate form of regulation, is the only effective method of [protection]."<sup>(10)</sup>

Courts will sometimes look to the motivation underlying a law to determine whether the stated reasons for regulation are a pretext for economic protectionism. Further, regulations which impose unduly burdensome requirements on out-of-state residents may be invalidated under the Commerce Clause. A licensure procedure may not impose charges or expenses greater than reasonably necessary to defray the administrative cost involved nor may it impose residence or other requirements that make it impossible for out-of-state professionals to comply.<sup>(11)</sup>

Because telemedicine consultations affect the health and well-being of individuals physically located in the state, states arguably have a legitimate local interest in ensuring that out-of-state telemedicine health professionals meet the same standards as professionals licensed within the state. The extent to which a particular telemedicine statute imposes burdens on out-of-state providers and interstate trade would have to be weighed against the benefits of regulation and the reasons for the regulation.

## Federal Authority

Despite the states' clear authority to license health care professionals, the Federal government does have the authority to establish national licensure standards. The Medicare and Medicaid programs, which include conditions of participation for nursing

### Box 12: State Authority Limitations

The Commerce Clause of the Constitution limits states' ability to erect barriers against interstate trade and the practice of health care has been held to be interstate trade for the purposes of antitrust laws

homes and other providers, establish specific standards of practice under their respective programs. In addition, Congress has previously passed laws establishing health and safety standards which affect interstate commerce. For example, Congress passed the Mammography Quality Standards Act (MQSA) of 1992, the Occupational Safety and Health Act of 1970, and the Clinical Laboratory Improvement Amendment of 1988. The Mammography Quality Standards Act allows the FDA to establish national standards for mammography facilities. States cannot mandate lesser mammography standards but can mandate standards that are stricter than those required under MQSA.

The Supremacy Clause of the Constitution preempts state laws that interfere with, or are contrary to, the laws of the Federal government.<sup>(12)</sup> But there is a strong presumption against preemption.<sup>(13)</sup> The Supreme Court has acknowledged that the regulation of health and safety matters has primarily and historically been a matter of exclusive state concern, and therefore preemption of state law should not occur in the absence of Congress' clear intent to supersede the state law.<sup>(14)</sup> However, the Supremacy Clause mandates that even state regulation designed to protect vital state interests must give way to paramount Federal legislation.<sup>(15)</sup>

Should Congress desire to regulate telemedicine licensure, it could do so. But Federal preemption of state law should not occur in the absence of Congress' clear intent to supersede the state law.

Congress' intent to preempt state law must be explicitly stated in the statute's language or implicitly contained in its structure and purpose.<sup>(16)</sup> In the absence of explicit pre-emptive language, courts have implied pre-emption in two situations. The first example exists where the scheme of Federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it."<sup>(17)</sup> The second example exists where "compliance with both

Federal and state regulations is a physical impossibility"<sup>(18)</sup> or when the purposes behind the two regulations are inconsistent.

Should Congress desire to regulate telemedicine licensure, it could do so. States would be able to continue their own licensing systems in the absence of complete preemption and to the extent that the purpose of a state licensing scheme does not interfere with the purpose or methods by which the Federal statute is designed to reach its goal, states would be able to continue their own licensing systems. If Congress decided to completely appropriate licensure of the telemedicine industry for the Federal government, any state action in that area would likely fail no matter how well it agrees with the Federal action and policies. Thus, the ultimate question of preemption will lie with the intent of Congress.

### Regional/Multi-State Authority

Under our Federal form of government, states are sovereign authorities that maintain those powers not ceded to the Federal government. The U.S. Constitution recognizes the states' authority to enter into compacts

or agreements with one another subject to the consent

#### Box 13: Interstate Compact example

An example of a compact in the health field is the Interstate Compact on Mental Health that requires states to treat mental health patients according to clinical need rather than on the basis of residence.

of Congress.<sup>(19)</sup> "An interstate compact is an agreement between two or more states established for the purpose of remedying a particular problem of multi-state concern."<sup>(20)</sup> The interstate compact enables states to accomplish what they could not do alone because of lack of control over the entire subject matter or lack of resources. (See Box 13)<sup>(21)</sup> Interstate compacts have been used to settle jurisdictional issues, establish uniformity in the regulation of people or goods, determine rights to property, taxes or natural resources, and to establish formal cooperative arrangements between state agencies for the provision of services

In areas traditionally left to the Federal government, states must seek Congressional consent to a compact. A compact is enforceable as a contract and will supersede all other conflicting state statutes, whether enacted prior or subsequent to the compact. The compact may not be modified nor revoked without the consent of the member states.

Regional or multi-state solutions to facilitate the delivery of interstate medical services are currently being explored by the Western Governors Association, whose Telemedicine Action Report recommends the establishment of a task force to draft a "Uniform State Code for Telemedicine Licensure and Credentialing."

### Standards

One of the primary functions of a licensure system is the establishment of academic and clinical competency standards for the practice of the profession. The licensure authority must ensure that those entering the profession are academically qualified, competent, and mentally and physically fit to provide

the activities covered by the license. There has been some harmonization of standards and objective criteria, including educational and training requirements, for the practice of medicine among the states, but important differences remain.

In particular, the definition of the "practice of medicine" greatly varies from state to state, further compounding the question of what licensure actually permits or requires a clinician to do. These differences in these definitions and their dependent standards may impose difficulties on health professionals seeking to practice telemedicine across state lines. In addition to the need to become licensed in numerous jurisdictions, physicians and other health professionals may be subjected to inconsistent or conflicting disciplinary standards.

### Enforcement

A licensure system must provide effective monitoring of the clinicians' competency and professional conduct, respond to the information brought to it by patients and health professionals, and provide a means to investigate and adjudicate complaints against a health professional. A licensure authority must have the means to hold the clinician accountable for his or her actions and enforce the authority's disciplinary decisions.

However, whether a state has the authority to enforce its licensure regulations against unlicensed out-of-state health professionals is unclear. For example, in the case of a physician practicing in a state where s/he does not hold a license, the physician's "home" state board may or may not take disciplinary action after a complaint is lodged. (See Box 14 )

The courts have not ruled on the issue of whether a state has jurisdiction over an out-of-state health professional offering telemedicine services to a patient located in that state. Before a state has the power to regulate an out-of-state health professional, the state must have legal jurisdiction over the person or entity<sup>(22)</sup>. A person's presence in a state is not required for a state to have jurisdiction over him or her. For the purposes of telemedicine, the question of legal jurisdiction may turn on the extent to which an out-of-state clinician takes affirmative action to establish contacts in the state<sup>(23)</sup>. For example, frequent transmissions into the patient's state and the solicitation of referrals from the state will likely be considered as evidence that the health professional is availing him or herself of the state's jurisdiction. Ultimately, the question of jurisdiction may require a balancing of how often and in what context the provider has conducted business in the jurisdiction.

### Administration

In addition, a licensure system must be able to administer and enforce its standards. The system should efficiently issue licenses, monitor activities and enforce its standards without imposing unnecessary burdens on licensees or the public. In addition, the licensure and enforcement process should be consistent and fair.

States' requirements for licensure often differ between states. The process for any one license can be time consuming, as shown in the case of physician license requirements (See Box 15)

States generally accept passing scores on the United States Medical Licensing Examination (USMLE) administered by the National Board of Medical Examiners, the American Board of Osteopathic Medicine Examination (ABOME) or the Federation Licensure Exam (FLEX) for initial applicants.

In addition, some states require that an oral exam be taken, while other states will accept FLEX scores only for examinations taken in the last five or ten years.

According to the Federation of State Medical Boards of the United States, a passing grade on the USMLE is the current standard for physicians for "all applicants for medical licensure in all jurisdictions in the United States."

**Box 15: Physician License Requirement Example**

When physicians apply for an initial license or endorsement of a license, they routinely must present original or certified transcripts, diplomas, test scores, birth certificates and other personal data, and may have to submit to an interview.

Each state has its own requirements for which documents must be presented, how many copies, the accompanying fees and the time line for processing. Complying with these various laws can be time-consuming and expensive.

States likewise maintain their own policies and procedures crucial to the effective functioning of the licensure system with respect to disciplinary proceedings, i.e. whether a hearing is required, the notification that must be provided, opportunity for rebuttal and the taking of evidence.

There are numerous procedural issues that must be addressed by any licensure authority. A few include: who determine whether an

applicant is qualified to practice medicine--an individual or a board; what credentials must be presented; are initial applicants treated differently from those already licensed in another state; what due process protections are in place to ensure that licensees are given a fair opportunity to respond to disciplinary charges; and, what fees are necessary to administer the system and how will they be collected and distributed?

The latter issue is of particular concern to some states where licensure fees provide a significant contribution to state revenues. These concerns have further relevance in discussion of national or Federal licensure models that would not only redistribute authority but also could significantly redistribute revenues away from the states.<sup>(24)</sup> Clearly, the efficient administration of the licensure system is a difficult but critical task.

## D. ALTERNATIVE APPROACHES TO LICENSURE

Most states require physicians to obtain a full and unrestricted license in order to offer medical services in that state. As noted above, a number of states have recently enacted licensure laws or regulations that explicitly affirm the requirement for a full license to practice in that state.

Currently there are a variety of alternative models relating to licensure that could be applied to a health professional providing only telemedicine services. A number of these models are available for review. Some of these models would vest partial or full authority to set standards and administer the licensure process in bodies other than the states. Some models would set uniform standards for credentials, professional conduct and discipline. Most models would provide specific mechanisms for enforcement proceedings against out-of-state health professionals. The following listing provides both a generally agreed upon working definition of the various terms related to licensure activities as well as a brief discussion and analysis.

### Consulting Exceptions

Most state medical practice acts contain consultation exceptions to their licensure which allow a physician who is unlicensed in a particular state to practice medicine in that state at the behest 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. Regular or frequent consultation may require the out-of-state physician to obtain a license. State medical boards have not defined consultation by regulation and have instead applied the term on a case-by-case basis. While telemedicine consultations could arguably fall within many of these consultation exceptions, a number of states have interpreted their consultation exceptions to preclude the practice of telemedicine.

Consultation exceptions to the licensure laws were enacted in most states before the advent of telemedicine. Although they may be well-suited to some telemedicine situations, it is unlikely these

exceptions were intended to apply to regular, on-going telemedicine links. State legislatures or medical boards could amend these exceptions to clarify under what circumstances they apply to telemedicine.

## **Endorsement**

Licensure by endorsement is currently used by most state boards to grant licenses to health professionals licensed in other states that have equivalent standards. For example, many 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. At a minimum, health professionals seeking licensure by endorsement must submit an application, original transcripts, letters of recommendation and fees to the state board for review and approval. Each state retains separate disciplinary authority over its licensees. Endorsement allows states to retain their traditional power to set and enforce standards that best meet the needs of the local population. However, for multi-state health professionals, the burden of complying with diverse administrative requirements and standards of professional conduct may be time-consuming and expensive. To the extent that standards and procedures are harmonized, these burdens become less prohibitive.

## **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. This approach has been adopted by the European Community and Australia to enable the cross-border practice of medicine. 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 deemed essential to the health care system. The health professional secures a license in the home state and is not required to obtain additional licenses to practice in other states. The health professional must, however, inform the other states of his or her intent to practice therein. Mutual recognition requires the participating states to agree to a common harmonized set of standards governing qualifications, conduct and discipline. However, the process by which mutual recognition is administered could vary.

For example, if we examine the case of physicians, mutual recognition could allow registered physicians to engage in the full range of medical practice or limit practice to a defined scope, such as providing medical services via telecommunications only. Enforcement authority could be structured to enable the host to investigate and sanction a registered physician or the host could be limited to suspending the physician's right to practice in the host state pending disciplinary proceedings by the home state. Once a physician's license is revoked by one state, it might be revoked automatically in all other jurisdictions, or revocation could depend upon separate proceedings in each state.

These issues of standards, enforcement and administration would have to be negotiated in any mutual recognition system. Such negotiations likely would be time consuming and complicated. Over the years, states have established standards, administrative procedures and enforcement mechanisms suited to the particular needs of the local population. Whether states would be willing to accept higher or lower standards than they currently have is uncertain. This is one of the issues that groups like the Western Governors Association would need to address to develop a network approach to licensure.

## **Reciprocity**

Reciprocity denotes the relationship between two states when each state gives the subjects of the other certain privileges, on the condition that its own subjects shall enjoy similar privileges at the hands of the latter state. 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 conducted on a bilateral or multilateral basis. A license valid in one state would give privileges to practice in all other states with which the home state has agreements.

No states are currently parties to a reciprocity agreement, although reciprocity arguably occurs now when patients physically travel to distant states to receive care. The process of negotiating bilateral or

multilateral agreements between pairs or groups of states would be time consuming and complicated. Reciprocity does not require a harmonization of standards or procedures, thus leaving health professionals subject to diverse requirements. A regional approach to reciprocity could be an incremental step toward standardization of the licensure process.

## **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 therein. By so registering, the clinician would submit to the legal authority and jurisdiction of the other state. Health professionals would not be required to meet the entrance requirements imposed upon those licensed in the host state, but they would be held accountable for breaches of professional conduct in any state in which they are registered.

California has passed legislation that would authorize registration but has not yet implemented it. There are currently no other licensure systems utilizing registration. Issues which would have to be addressed under a registration system include the appropriate process for disciplining out-of-state health professionals, the administrative procedures for registration, and issues of professional conduct where standards vary from one state to the next, i.e. patient record-retention and confidentiality requirements. Registration should be less burdensome than current licensure requirements, but will affirmatively assert jurisdiction over out-of-state health professionals and make it easier to hold them liable for their conduct. Further, some protections may be necessary to guard against health professionals obtaining a license in the easiest jurisdiction with the lowest requirements and merely registering elsewhere.

## **Limited Licensure**

A limited licensure system would be a modification of the current system. Health professionals would be required to obtain a license from each state in which they practiced. However, the health professional would have the option of obtaining a limited license that allows the delivery of a specific scope of health services under particular circumstances. This system would limit the scope of practice rather than the time period for practice as is currently the case with some consultation or emergency exceptions. The health professional would be required to maintain a full and unrestricted license in at least one state. Presumably, the administrative process for obtaining a limited license would be somewhat less burdensome than for full licensure. Each state would continue to establish its own standards for licensure.

Limited licensure requires each state legislature, acting on its own, to adopt such a system. Limited licensure could reduce the administrative burdens on out-of-state health professionals who would otherwise obtain a full license. Clinicians will continue to confront the hurdle of trying to comply with disparate state licensure requirements because each state would continue to establish its own standards for licensure.

## **National Licensure**

A national licensure system could be implemented at the state or national level and would involve the issuance of a license based on a standardized set of criteria for the practice of health care throughout the U.S. Administration of this system at the national level could be left to a national professional organization. Central administration might raise concerns over state revenue loss, the legal authority of the states, the mechanism for financing the system, and the logistics of where and how confidential licensing data would be collected, processed, and stored. Disciplinary actions would continue to be carried out at the state level subject to the national standards.

**Box 16: National Licensure Could be Implemented at the State or Federal level**

If national licensure is implemented at the national level, national standards could simplify the application process for multi-state health professionals while leaving responsibility for enforcing these standards to the States.

A state implemented national licensure system would require states to voluntarily incorporate the national standards into their laws. In such a system, the states would be unable to impose significant additional standards. Health professionals would still be required to obtain a license from every jurisdiction in which they practiced, but a common set of criteria would greatly facilitate the

If implemented at the state or local level these issues could be simplified since states could

retain control. In either case, these national standards would require states to agree on a common set of standards that encompass everything from qualifications to discipline.

**Federal Licensure**

Under a Federal licensure system, health professionals would be issued one license by the Federal government based upon Federally established standards related to qualifications and discipline. This license would be valid throughout the United States. These Federal regulations would preempt existing state licensure laws. A Federal licensure system could be administered through Federal agencies either at the national or local level, or through the states.

The establishment of uniform standards and procedures at the Federal level may ease the administrative burden on clinicians. However similar logistical and administrative problems would occur with the central administration of a Federal licensure system and enforcement activities carried out at the Federal level would likely be difficult.

Under these circumstances, states may be charged with implementing the system. This creates some questions noted above about how such a system would be funded and how administrative and disciplinary responsibilities would be paid for and carried out. Further implementation of Federal standards removes the states' traditional authority to set standards reflective of the demographics, practice patterns and procedural needs at the local level.

**E.LEGAL AND REGULATORY ISSUES RAISED BY THESE MODELS**

A major purpose of licensing health care professionals is to protect the public from those who are incompetent or impaired. To be effective, a licensure system must have the standards and resources to ensure that health professionals are clinically competent in their chosen specialty, as well as mentally and physically fit to render services to the public, identify impaired health professionals, resolve patient complaints, and prosecute health professional misconduct. The system must also provide due process guarantees for licensees and applicants. Not all licensure models are equally suited to accomplishing all of these tasks.

States would continue to play a primary or critical role in most of these models. Models that leave power to the states must rely upon voluntary state participation for their success.

In the case of physician licensure, state standards have been harmonized to some extent. (See Box 17) However, administrative procedures and some standards of professional conduct remain disparate. In fact, over the past two years, state laws governing interstate medical activity have become increasingly diverse as state legislatures enact different language to address concerns regarding telemedicine. Without an agreed-upon set of standards, there will continue to be disparate state medical practice acts and

**Box 17: States Harmonize Some Standards**

For example, all state medical boards require physicians to be a graduate of an accredited medical school, to have passed the U.S. Medical Licensure Examination and to be judged "fit" to practice medicine. Likewise, state medical boards have substantially similar grants of authority to investigate and adjudicate complaints against license holders

statutes. This lack of coordination presents difficulties for health professio

whose practice extends into many states. On a practical level, the difficulty in negotiating bilateral or multilateral agreements must be recognized.

At the same time, telemedicine may greatly increase the number of interstate consultations and the risk that patients will obtain services from individuals whose qualifications cannot be easily verified. Any changes in the licensure system should ensure that a "lowest common denominator" standard of health care is not developed that enables the least competent health professionals to simply relocate to the state with the lowest standards.

Models that formally grant licenses or recognize out-of-state health professionals will give states jurisdiction over out-of-state health professionals. While all of these models seek to hold health professionals accountable for their actions, the level of interest states will have in disciplining out-of-state health professionals who only occasionally see patients in the state is uncertain. Their disciplinary actions will certainly be influenced by the resources available to them. The concern over economic issues will continue to be a key factor as systems that eliminate fees from the issuance and renewal of multiple licenses may leave states with fewer resources to fulfill their administrative and disciplinary functions.

## F. SPECIFIC REFORM PROPOSALS

A number of states and organizations are examining licensure alternatives for telemedicine. A few of the more widely-known models are outlined below.

**California Registration Bill.** On September 24, 1996, California enacted a law which gives the state medical board the discretion to develop a proposed registration program to permit out-of-state physicians to practice telemedicine in California<sup>(25)</sup>. The proposed registration program is intended to be implemented by future legislation. The registration program would discipline health professionals who allow unregistered persons to practice telemedicine in California as well as discipline registrants who violate the licensure requirements of other jurisdictions. The registration program may include standards for confidentiality and format of medical records, registration fees and consumer education.

**American College of Radiology.** In 1994, the American College of Radiology (ACR) adopted a "Standard for Teleradiology" which includes the recommendation that "physicians who provide the official, authenticated interpretation of images transmitted by teleradiology should maintain licensure appropriate to delivery of radiologic service at both the transmitting and receiving sites." The ACR has developed a model act based on this standard which is similar to the current endorsement mechanism utilized by state licensure boards. In addition to licensure and credentialing, the ACR Standard provides for the appropriate storage of images, delegates responsibility for ensuring the quality of transmitted images, and establishes quality control and equipment standards for teleradiology.

**American Medical Association.** The American Medical Association (AMA) House of Delegates voted in June 1996 to adopt a policy that "states and their medical boards should require a full and unrestricted license for all physicians practicing telemedicine within a state." The policy went on to say that application requirements are to be "non-burdensome, issued in an expeditious manner, have fees no higher than necessary.....and that utilize principles of reciprocity with the licensure requirements of the state in which the physicians in question practice." The final resolution adopted by the AMA differed from that recommended by the Joint Report of the Councils on Medical Education and Medical Services which proposed that states should adopt a "special license" for telemedicine health professionals. The AMA also adopted a resolution calling for the Board of Trustees to "study the ethical and legal questions

raised by new communications technologies as they relate to medical practice, including the worldwide web, teleconferencing, physician-staffed phone services that provide medical advice to nonpatients, and open physician discussions of clinical matters on online services."

**College of American Pathologists.** The CAP has taken the position that "a physician rendering primary diagnosis and/or treatment should have a full and unrestricted license to practice medicine in the state in which the patient presents for diagnosis. In cases where specimens, slides or images are transported in interstate commerce, the patient is deemed to have presented for diagnosis in the state in which the specimen is taken or the image made." Like the above models, this proposal would require physicians to have their license endorsed in each state from which they receive patient specimens or information. The CAP suggests that patients and the delivery of care would be better served through an abbreviated licensure process as opposed to a license for a limited practice.

**Federation of State Medical Boards.** In October 1995, the Federation of State Medical Boards (FSMB) proposed "An Act to Regulate the Practice of Medicine Across State Lines." This model act would require physicians who regularly or frequently engage in the practice of medicine across state lines, by electronic or other means, to obtain a special license issued by the state medical board. Practice across state lines is defined broadly as "the rendering of a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient." As with limited licensure, physicians holding a special license would be prohibited from physically practicing medicine within the state unless a full and unrestricted license were obtained. It would subject the licensee to the Medical Practice Act of the issuing state, and to the regulatory authority of the state's medical board. Each state would have the option of denying such a special license but would be encouraged to issue the license if it found that the applicant would not present a threat to the public. The Model Act would narrow the consultation exception to ad hoc consultations which are neither compensated nor performed under a contractual relationship.

**National Council of State Boards of Nursing.** The National Council of State Boards of Nursing (NCSBN) has been examining alternative licensure models for nurses that would facilitate the interstate movement of nurses as well as the practice of telemedicine. Among the models under consideration are a multi-state licensure system administered by the states and a centralized licensure system administered under state authority via a multi-state compact.

## F. OTHER LEGAL ISSUES--PROFESSIONAL LIABILITY

Medical malpractice can be defined as professional misconduct in improperly discharging professional duties, or failing to meet the standard of care of a professional. Various definitions of standard of care and professional duties have been provided by statute, regulations, and case law. The diverse nature of these definitions and their sources are further complicated by jurisdictional issues when applied in the area of telemedicine. The additional problem of the time delay between the event leading to a malpractice claim and the filing of the claim means that some problems may take up to two or more years before they become apparent.

The Physician Insurers Association of America has concluded that malpractice claims require an average of 21 months following the alleged incidence of an adverse outcome to be reported. A number of basic questions will need to be addressed as telemedicine specific policy and procedures dealing with malpractice liability are formulated. Some of these have been raised in the preceding sections. Issues of choice of venue and law will need to be considered as states differ in their statutory limits on malpractice awards. This is certainly an issue in the development of a multi-state network system. Existing financial considerations affect both the individual health professional and the malpractice insurer.

The variety of types of services potentially deliverable through telemedicine will most likely require insurers to evaluate the need to develop new types of policies specifically for telemedicine based on the type of service being provided. Definitions will also have to be developed specifying what constitutes a physician-patient relationship under telemedicine. The specific definitions developed will have legal as well as quality of care implications. For example, the question of whether "distance medicine" imposes a new standard of care needs to be resolved. If face-to-face contact creates greater opportunity for better

diagnosis and communication between patient and the practitioner, then the telemedicine practitioner might be more vulnerable to suit. The effect of telemedicine on the subsequent development of a therapeutic relationship is also not currently defined. The IOM Report states that "Decision makers still do not have good enough information comparing the effects of telemedicine applications to those of alternative health care strategies for quality, access, cost and acceptability."<sup>(26)</sup> Such information will be essential in the development of an acceptable liability system to deal with the unique issues raised by this technology.

## G. NEXT STEPS

To date, most of the nation's telemedicine initiatives have occurred within states. This situation could rapidly change as the number and diversity of telemedicine services grow in many parts of the country where health care services do not follow geopolitical boundaries. Traditionally, patients go where the care is. As telemedicine is increasingly used to bring care to where the patient is, concerns about interstate licensure restrictions are bound to grow.

There are a variety of approaches to deal with the interstate licensure issues raised by telemedicine and although there appears to be substantial similarity among states with regard to the initial criteria required to obtain a license, significant differences persist. Currently these significant policy and procedural differences among states raise costly and time-consuming barriers for multi-state telemedicine providers seeking a license.

Although not strictly a legal issue, the related process of credentialing health care professionals has profound implications for telemedicine and has legal implications. "Credentialing" refers to the institutional (hospital, HMO) policy and procedures that determine whether a health care professional has the qualifications to be employed or be granted privileges to practice. This information is used in employment decisions, in granting clinical privileges and in the establishment of a practitioner's scope of practice (the range of services an individual may perform). This aspect of health professional regulation is not routinely conducted at the state or Federal level unless the professional is primarily employed by the Federal or state government. In some instances, however, state medical practice acts may specify requirements for credentialing. Traditionally the institutions in which the health professional is providing the service have taken this responsibility. Nationally accepted standards are provided by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Commission on Quality Assurance. Although intimately associated with licensure, the process of credentialing is a separate activity.

An unresolved issue is whether a telemedicine consultant needs to be credentialed at both his/ her home as well as at the remote institution for which attending health care professionals request consultation. If significant numbers of institutions are involved, a requirement for credentialing at each could create significant administrative burdens for both health care professionals and institutions. The JCAHO has no official policy, but it has issued one opinion stating that the consultant physician responding to a request for a referral does not have to be credentialed at the referring institution so long as the referring physician writes all orders that are in the patient's chart.

In the coming months, the JWGT will convene a group of interested parties, including representatives from the Federation of State Medical Boards, the National Council of State Boards of Nursing, the AMA, the Western Governors, the Center for Telemedicine Law, and National Governors Association, and the American Telemedicine Association, to explore next steps to ease licensure barriers between states.

In particular, the JWGT is very interested in stimulating the development of regional or multi-state licensure compacts that would provide models for future harmonization of licensure across the nation.

In addition, the JWGT will convene representatives from several health professional associations and credentialing bodies (e.g., specialty societies, the AMA, the American Nurses Association, Joint Commission on Accreditation of Health Care Organizations, and the American Psychological Association) to explore issues of credentialing of health care professionals in telemedicine.

## H.LEGAL ISSUES REFERENCES AND NOTES

1. H.R. 1555; 104th Cong., 1st Sess. (1995). The amendment originally referred to "licensed health care provider" rather than "licensed physician."
2. S. 2171, 104th Cong., 2nd Sess. (1996).
3. See, Appendix 1 for the state statutes and regulations pertaining to telemedicine.
4. April 13, 1995 Letter from Florida Board of Medicine to President of Florida Society of Pathologists (first reviews of electronic images, biopsies and pathologic specimens are not considered consultations); March 18, 1996 Letter from Iowa Board of Medical Examiners to Ellen S. Weinstein (medical reports used for 'primary diagnostic purposes' do not fall within state's consultation exception); Minutes of November 9, 1993 Executive Session of Maine Board of Medical Examiners (primary physician performing radiologic study must be licensed in Maine); September 18, 1995 Letter from Massachusetts Board of Registration in Medicine to Harry L. Greene, M.D. and Kevin B. Dole, M.D. (reading of biopsies by out-of-state physicians constitutes the practice of medicine); March 29, 1996 Letter from Pennsylvania Board of Medicine to Teleimaging Chartered (out-of-state physicians "who routinely perform telemedical services resulting in medical reports or opinions" regarding patients in Pennsylvania must be licensed by state); and April 22, 1994 Minutes of Legislative Committee of Virginia Board of Medicine (out-of-state physician doing primary interpretation of a radiology image for patient located in Virginia must be licensed in state).
5. Letter from Office of the Attorney General of Mississippi to P. Doyle Bradshaw, Executive Officer of the State Board of Medical Licensure, December 8, 1995. 1995 Miss. AG LEXIS 867 (Dec. 8, 1995).
6. *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 792 (1975); see, also, *Ferguson v. Skrupa*, 372 U.S. 726, 731 (1963); *Dent v. West Virginia*, 129 U.S. 114, 122 (1889).
7. "The Commerce Clause of the Constitution grants Congress the power '[to] regulate Commerce with foreign Nations, and among the several states, and with the Indian Tribes.' Art. I, 8, cl. 3. 'Although the Clause thus speaks in terms of powers bestowed upon Congress, the Court has long recognized that it also limits the power of the states to erect barriers against interstate trade.'" *Maine v. Taylor*, 477 U.S. 131, 137 (1986) (quoting *Lewis v. BT Investment Managers*, 447 U.S. 27, 35 (1980)).
8. See, e.g., *Arizona v. Maricopa County Medical Soc'y.*, 457 U.S. 332 (1982).
9. *Maine v. Taylor*, 477 U.S. 131. (Maine was allowed to prohibit import of baitfish in order to protect the health and integrity of native species. The Supreme Court found that no alternative, non-discriminatory means would achieve the state's legitimate objectives.)
10. *Maine v Taylor*, 477 U.S. at 150 (quoting *Lewis v BT Investment Managers, Inc.*, 447 U.S. 27, 43 (1980)).
11. *Mercer v. Hemmings*, supra.
12. U.S. Const. Art. VI, cl.2. The Supremacy clause states: "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."
13. The Supreme Court first recognized the Federal-state balance in *McCulloch v. Maryland*, 14 U.S. (4 Wheat.) 316, 427 (1819). Since that time, "it has been settled" that the doctrine of preemption constitutes the resolution between Federal and state law, and all "state law that conflicts with Federal law is without effect." *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S.

725, 746 (1981)).

14. *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 21 (1987).

15. *De Canas v. Bica*, 424 U.S. 351, 357 (1976).

16. *Cipollone v. Liggett Group*, 505 U.S. at 516. The Supreme Court held in *Jones v. Rath Packing Co.*, 430 U.S. 519, 525-26 (1977), that preemption depends upon "the relationship between states and Federal laws as they are interpreted and applied, not merely as they are written;" 375 U.S. 96 103 (1963); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); see also *Ingersoll-Rand Co. V. McClendon*, 498 U.S. 133, 138 (1990) (slip op., at 3) (stating that "[t]o discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute.").

17. *Jones v. Rath Packing Co.*, 430 U.S. at 525 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); see also *Fidelity Fed. Sav. & Loan Ass'n. v. De La Cuesta*, 458 U.S. 141, 153 (1982).

18. *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); see also, *McDermott v. Wisconsin*, 228 U.S. 115 (1913). (Wisconsin's syrup-labeling rules were such that if out-of-state syrup was labeled so as to comply with the Federal Food and Drugs Act, they syrup would be mislabeled under Wisconsin law. The Court barred enforcement of the Wisconsin regulations.)

19. U.S. Const. Art. I, Sec. 10, cl. 3, provides in pertinent part, "No State shall, without the Consent of Congress . . . enter into any Agreement or Compact with another State . . ."

20. Black's Law Dictionary.

*Note: The Supreme Court has opened the door to states having authority over commercial activity outside its borders. For example, the court has held that a state's regulatory jurisdiction could be asserted on the basis of contacts with the state through the mail. A state may argue that its interest in protecting its citizens justifies the imposition of regulations over out-of-state telemedicine providers even though there may be a low level of contacts with the state. In other situations where a party's only contact with the state has been by electronic transmission, courts have reached conflicting conclusions on the issue of jurisdiction.*

21. Zimmerman and Wendell, *The Law and Use of Interstate Compacts*, 1976.

22. A state may have jurisdiction over a defendant so as to require it to defend itself in that state, while at the same time not having jurisdiction over the defendant to regulate them. See generally, *Quill Corp. v. North Dakota*, 504 U.S. 298, 320-321 (1992).

23. It has been held that the type of contacts required for regulatory jurisdiction require "the connection between a state and the regulated person be of a more substantial character than the 'minimum contacts' needed to support judicial process running against the person." *Aldens v. La Follette*, 552 F.2d 745, 751 (7th Cir. 1977). On the other hand, it has also been held that "contacts that would justify regulatory provisions as to one type of business might not as to another because of the greater interest of the state in the former than in the latter." *National Liberty Life Ins. Co. v. State*, 62 Wis.2d 347, 215 N.W.2d 26 (1974).

24. Hutcherson, Carolyn. (Personal communication, September 19, 1996)

25. 1995 California S.B. 2098, signed by the Governor September 24, 1996.

## FOOTNOTES

1. H.R. 1555; 104th Cong., 1st Sess. (1995). The amendment originally referred to "licensed health care provider" rather than "licensed physician."

2. S. 2171, 104th Cong., 2nd Sess. (1996).
3. See, Appendix D for the state statutes and regulations pertaining to telemedicine.
4. See Legal Issues References and Notes.
5. See Legal Issues References and Notes.
6. *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 792 (1975); *see, also, Ferguson v. Skrupa*, 372 U.S. 726, 731 (1963); *Dent v. West Virginia*, 129 U.S. 114, 122 (1889).
7. See Legal Issues References and Notes.
8. See, *e.g., Arizona v. Maricopa County Medical Soc'y.*, 457 U.S. 332 (1982).
9. *Maine v. Taylor*, 477 U.S. 131.
10. *Maine v Taylor*, 477 U.S. at 150.
11. *Mercer vs. Hemmings*, *supra*.
12. U.S. Constitution Art. VI, cl.2. (See References and Notes)
13. See Legal Issues References and Notes.
14. *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1,21 (1987)
15. *De Canas v. Bica*, 424 U.S. 351,357 (1976)
16. *Cipollone v. Leggett Group*, 505 U.S. at 516.
17. *Jones v. Rath Packing Co.*,430 U.S. at 525
18. *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)
19. U.S. Const. Art. I, Sec. 10, cl. 3, provides in pertinent part, "No State shall, without the Consent of Congress . . . enter into any Agreement or Compact with another State . . ."
20. Black's Law Dictionary.
21. Zimmerman and Wendell, *The Law and Use of Interstate Compacts*, 1976.
22. See Legal Issues References and Notes
23. Ibid
24. Hutcherson, Carolyn (Personal communication, Sept 19, 1996)
25. 1995 California S.B. 2098, signed by the Governor, September 24, 1996. (See Appendix D)
26. Institute of Medicine: "Telemedicine:A Guide to Assessing Telecommunications in Health Care", 1996.

# TELEMEDICINE REPORT TO CONGRESS

January 31, 1997

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## PAYMENT FOR TELEMEDICINE SERVICES

### A. OVERVIEW

The current lack of payment for telemedicine services is considered to be one of the major barriers to telemedicine's rapid deployment. For example, most third party payers have taken a "wait and see" approach toward telemedicine payments. On the Federal government side, Medicare and Medicaid, which are wholly or partly administered by the Health Care Financing Administration (HCFA), have varying policies covering telemedicine. Under Medicare, if standard medical practice does not require face-to-face contact between patient and health professional, then it will cover the service, as in the case of teleradiology. Medicaid coverage for telemedicine varies from state to state. Thus, health professionals and services that are covered vary greatly by state.

On the private sector side, very little information exists about private payer coverage of telemedicine. Evidence to date<sup>(1)</sup>, however, suggests that few private payers cover telemedicine consultation services, although most cover radiology and similar imaging services. Regardless of the payers involved, the major issue is whether any additional benefits provided to patients and health care professionals by telemedicine are worth the potential additional costs. This is of particular concern to the Medicare and Medicaid programs which are facing consistent threats to their financial solvency.

Given the lack of substantial information concerning the private sector's involvement in telemedicine payment, this chapter's discussion focuses largely on the Medicare and Medicaid programs, where the Federal government has a direct role in policy making. In Section B we discuss these programs; in Section C, we touch briefly upon private payer coverage and in Section D, we discuss some of the concerns that third party payers see as barriers to reimbursement. Finally, in Section E, we look at some of the future directions for the JWGT's involvement in the ongoing discussions on telemedicine payments.

### B. MEDICARE AND MEDICAID

Telemedicine advocates have called for payment of telemedicine by the Medicare program because Medicare is the largest health insurance program in the United States and, as a result, the private sector generally follows its lead. According to statute, the Medicare program covers only those health care services and procedures that are determined to be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"<sup>(2)</sup>. Coverage

**Box 18: HCFA's Demonstration Project**

In early October 1996, Medicare announced that it will begin limited payments for Telemedicine consults in four states under its waiver authority—Georgia, Iowa, North Carolina, and West Virginia. The demonstration is for fee-for-service payments to a limited number of facilities in each state, not all the facilities providing Telemedicine within the states. The demonstration will be carefully evaluated to assess the impact of Telemedicine on the cost and quality of services provided to Medicare beneficiaries. This evaluation will be carefully coordinated with the Office of Rural Health Policy's evaluation of rural Telemedicine programs.

is not available for experime or investigat technolog Despite these restriction and its concerns about increased

volume cost, technology costs, efficacy, quality, as well other issues highlighted in Section III, HCFA recognizes that telemedicine holds great promise for breaking down barriers to quality medical care, particularly specialty care in rural underserved areas. Telemedicine may also save health care expenditures for beneficiaries, providers, and payers through reduced costs for patient and/or health professional travel, medical education, interhospital transfers of patients, and patient record keeping. Thus, Medicare is helping to finance several studies and projects that examine the clinical and cost effectiveness of telemedicine. HCFA has awarded nearly \$9 million from its appropriated funds to related research and demonstrations. These studies are closely coordinated with those of the ORHP, which is collecting broad evaluative information on rural telemedicine programs and on other agencies such as AHCPR and NLM. We also note that the Health Insurance and Portability Act of 1996 calls for HCFA to "...submit a report to Congress on Medicare reimbursement for telemedicine services no later than March 1, 1997 (which shall) include a proposal for Medicare reimbursement of such services." Unfortunately, since HCFA's three-year demonstration is barely underway, little data from this initiative will be available for inclusion.

### Medicare Fee-for-Service Coverage and Payment

Medicare defines physicians' services as "a service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgement." Therefore, payment from the Medicare trust funds is limited to those telemedicine applications where, under conventional health care delivery, face-to-face contact is not required between

**Box 19: What Medicare Covers**

Medicare covers teleradiology, which is the most widely used and reimbursed form of Telemedicine. Direct visualization would be possible by means of X-rays, electrocardiogram (ECG), electroencephalogram (EEG), etc. The interpretation by a physician of an actual ECG or EEG reading that has been transmitted via telephone (i.e., electronically rather than by means of a verbal description) is a covered service.

patient and physician. Thus, Medicare covers teleradiol as well as long

distance ECG and EEG interpretations. (See Box 19) By contrast, Medicare does not cover consultations and other physicians' services delivered through telecommunications because, under the conventional delivery of medicine, those services are furnished in person.

### Medicaid Fee-for-Service Coverage and Payment

#### Coverage of Medicaid Telemedicine Applications

Telemedicine has only recently been introduced to Medicaid through the innovative programs of individual states. Operating within the broad parameters of Federal laws and regulations, each state establishes its own eligibility standards; determines the type, amount, duration, and scope of services; and sets the rate of payment for services. Typically, when establishing coverage criteria for services, states consider factors such as the availability of less expensive alternative treatments, conformance with commonly accepted health care procedures, and the safety and effectiveness of the service. States have utilized telemedicine technology for a number of different medical services. Radiology and interactive video consultations remain the most frequent uses of telemedicine under Medicaid; as technology improves, dermatology, digitized mammograms, neurosurgery, and pathology are also likely to be considered for Medicaid coverage. Transmitting CAT Scans, MRIs, and ECGs for review and

**Box 20: Medicaid State Coverage**

Medicaid programs in ten states currently cover some telemedicine services. They are:

- |              |                             |
|--------------|-----------------------------|
| Arkansas     | California*(effective 1997) |
| Georgia      | North Dakota                |
| New Mexico   | Montana                     |
| South Dakota | Utah                        |
| Virginia     | West Virginia               |

Since Medicaid does not mandate the face-to-face encounter required in Medicare, a waiver is not needed for states to add Telemedicine to their Medicaid programs.

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telemedicine also has gained increasing popularity in the provision of mental health and substance abuse services for Medicaid beneficiaries. For example, the Montana Medicaid program has been a leader in supporting telemedicine for providing these services to patients who are frequently more than 100 miles away from the nearest mental health or substance abuse practitioner. Nancy Ellery, Administrator of the Health Policy and Services Administration of Montana, believes that telemedicine has saved the state substantial transportation and other costs, while expanding access for rural Montana residents.

**Box 21: Telemedicine Savings**

Montana Officials use their telemedicine network extensively for mental health consultations and services. In fiscal year 1995, it estimated that use of Telemedicine save patients \$65,000 in travel time, lost wages, food and lodging. Says Nancy Ellery, "Based on what we've seen so far, we think it provides improved access for people who live in rural communities, lower costs to the program and access to better quality care."

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state Medicaid agencies decide whether or not to cover and reimburse for services furnished through telemedicine applications as an optional cost-effective alternative to direct consultations or examinations. Reimbursement for all Medicaid covered services, including those that employ telemedicine applications, must satisfy Federal requirements of efficiency, economy, and quality of care; and states are required to utilize the least costly means of providing quality health care services. States are also encouraged to use the flexibility inherent in the Federal guidelines to create innovative payment methodologies in reimbursing services that incorporate telemedicine technology. For example, states covering health care services under Medicaid that utilize telemedicine may develop a number of different strategies for reimbursing both the health professional (specialist) at the hub site for the consultation and the health professional caring for the patient at the spoke site for the office visit.

Telemedicine services also involve expenses that are not traditionally billed to Medicaid for medical services, such as equipment and transmission costs. While the cost of electronic transmissions may not be separately billed to Medicaid, these costs could be justifiably incorporated into the fee for a coverable service.

**Medicare Managed Care**

The use of telemedicine/telecommunications networks and techniques in the Medicare managed care program can be viewed as a means of:

- increasing access to quality health care for rural and under-served Medicare beneficiaries;
- reducing distance and isolation in patient/ practioner encounters, and;
- developing a baseline of information for on-going evaluation of utilization and outcomes.

Telemedicine is viewed by HCFA as a potential change agent and more managed care plans, hospitals, and practitioner groups are contacting the agency about grants and contracting options for developing telemedicine networks.

HCFA has recently informed managed health care plans and Federally qualified health maintenance organizations with TEFRA(3) risk based contracts, that they do not need a waiver to offer telemedicine services. Such plans, however, would not receive additional reimbursement for covering telemedicine services. HCFA's primary goal in establishing the risk contracting program was to reduce Medicare's growing financial exposure by paying managed care plans 95% of comparable costs under fee-for-service. These risk contracting plans are expected to promote healthy lifestyles, disease prevention and apply increased efficiencies in coordinating the delivery of health care services to offset the loss in Medicare revenue. For this reduced rate, risk contracting plans are expected to deliver all Medicare covered services and such other additional or optional services that the plan may elect to provide such as telemedicine. Funding of ongoing operational costs, including connection, transmission and equipment maintenance can be allocated under administrative and marketing expenses in managed care proposals forwarded to HCFA for contract consideration. To the extent that equipment acquisition costs can be amortized, these too can be reflected in itemized expenses.

**Medicaid Managed Care**

The number of states enrolling Medicaid recipients into managed care has greatly increased over the past few years. Facing fiscal pressure due to the explosive growth in their Medicaid populations and the growing cost of medical care, states are responding to these pressures by developing Medicaid managed care programs.

In general, when a state Medicaid agency contracts with a managed care plan, no mention is made in the contract about coverage or payment for telemedicine services. Thus, it is usually left to the managed care plan to decide whether or not to utilize telemedicine.

**Medicaid Waivers**

A limited number of states are testing new approaches to their Medicaid programs by obtaining waivers of statutory requirements and limitations from the Secretary of the Department of Health and Human Services. In obtaining waivers, many states incorporate managed care as the delivery system to Medicaid beneficiaries.

Two states in particular are working to develop a telemedicine network within their waiver programs. For example, Oklahoma has used the waiver program to link rural health professionals with their urban counterparts. (See Box )

The state of California is also interested in using telemedicine in their managed care programs. The state's legislature has recently passed legislation that would cover telemedicine and has consulted with HCFA's San Francisco Regional Office for technical advice. The areas the state has considered using telemedicine for are: practitioner consultations, second opinions in the delivery of specialty services, or for diagnosing or treating rare or more complex medical conditions. Because both managed care and telemedicine are such new areas to some states, there has not been much thought to coordination of the two.

**Box 22: Oklahoma State Waiver Example**

With a Medicaid waiver application known as Sooner Care, Oklahoma is trying to expand the use of telemedicine to its rural communities. The state is building a telemedicine infrastructure that will link rural providers with their urban counterparts. Oklahoma believes this initiative can greatly facilitate the ability of rural providers to construct locally operated managed care plans by giving them access to essential diagnostic and specialty services. It will also serve as a vehicle for urban providers and health plans to build relationships in rural areas and to foster expansion operations.

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## Payment by Private Sector Fee-for-Service

From a review of the literature, HCFA was able to identify only one private insurer that currently has a formal policy to pay for telemedicine services beyond case-to-case considerations: Blue Cross/Blue Shield of Kansas pays for certain services furnished by physicians licensed to practice in that State.<sup>(4)</sup> Anecdotal information indicates that at least two other Blue Cross/Blue Shield plans in Montana and West Virginia have paid for telemedicine services on some occasions. Other insurers may pay for telemedicine on a fee-for-service basis but they have not been specifically identified as such. For example, the Health Insurance Association of America (HIAA) recently completed a periodic survey of members. The survey was sent to 120 insurers, of whom 53 responded. The survey found that 15 percent of the respondents pay for physicians' professional services furnished through telecommunications media. More specific information about the type of services and costs was unavailable.

In addition to HCFA's findings, the ORHP/Abt Associate's study has attempted to identify the extent of private third party coverage of rural telemedicine. At the time of the survey, approximately 8% of the telemedicine facilities reporting had successfully negotiated payment with private third-party payers.

### Coverage and Payment by Private Sector Managed Care Plans

The interest in telemedicine by the private sector managed care plans primarily stems from the reality that this technology may be the most effective way for plans to penetrate, expand or hold their market share in rural, under populated areas. The availability of telemedicine may be a tool by itself to facilitate marketing of plans. Telemedicine also has the potential to decrease costs associated with: health care professional travel, patient transfers between hospitals, duplication of records and overhead costs such as excess paper and film.

#### Box 23: Telemedicine Can Increase Profits

A Columbia-HCA Hospital in Erin, Tennessee is crediting teleradiology with improving its bottom line and increasing the range of services available to local citizens.

The 40-bed hospital used telemedicine technology to create a link with a 18-member radiology group in Nashville, 72 miles away. That allowed the hospital to expand its partial radiology coverage from two hours, two days a week to full-time. The teleradiology link has also helped the hospital increase its market share from 24 to 74 percent and increase revenues by \$250,000. Outpatient visits have jumped from 600 per day to over 1,000.

Despite these inducements the managed care community has been slow to deploy telemedicine. However,

there are a growing number of successful managed care models that have recently begun utilizing telemedicine applications. Two of these plans are Allina Health Systems of Minneapolis, MN and Methodist Hospital of Indianapolis, IN. Allina Health Systems is a large managed care provider in Minnesota and Wisconsin. Its telemedicine network was formed with the Rural Health Alliance, a group of rural communities in central Minnesota, and currently consists of 15 rural and 7 urban sites. Allina anticipates adding three to five additional sites per year.

An even more important trend to watch are changes made by the states of California and Louisiana. Louisiana recently passed a law dealing with telemedicine reimbursement that

specifies a certain reimbursement rate for physicians at the originating site and also includes language prohibiting insurance carriers from discriminating against telemedicine as a medium for delivering health care services. California also recently passed California State Bill 1665 (1996) requiring private managed care plans to establish policies regarding coverage of telemedicine services.

## D. ISSUES AND CONCERNS

The absence of more widespread reimbursement payments for telemedicine is the result of many factors and concerns. Although telemedicine has the long term potential to improve patient access to the best health care possible, it presents a host of issues and concerns for payers such as efficacy, quality, technology cost, volume of care and potential over utilization--just to name a few. Box 24 highlights some of these issues.

It is important to point out that, regardless of any cost savings that may be gained from telemedicine, greater access to medical care, particularly specialty care which involves expensive diagnostic and therapeutic procedures, could very likely generate greater expenditures for payers. In the private sector, added expenses resulting from broadened coverage and new technologies are financed by higher enrollees premiums. For Medicare, growth in spending is of critical concern because of its effects on the continued viability of the program and the implications for the Trust Funds. As a result, Medicare increases in spending associated with telemedicine coverage may have to be at least partially absorbed by reductions in expenditures for other services.

## **E. NEXT STEPS**

The overall benefits to society that telemedicine could potentially bring in terms of greater access, more efficient delivery and lower hospitalization costs must be weighed together with potential additional costs. While the advent of new technologies, aimed at improving access to care is welcomed, it is important to ensure that these technologies are used in appropriate ways that benefit the patient, are consistent with good medical practice, and represent a wise investment of taxpayer resources.

The survival of telemedicine in this country ultimately rests, in part, on ensuring a steady funding stream through payments for telemedicine services. However, although necessary, these payments are unlikely

**Box 24: Insurer Concerns About Telemedicine Payments**

**Efficacy and Quality.** Insurers normally do not pay for unproven medical procedures yet many aspects of telemedicine remain investigational or experimental. At this time, generally accepted safety and efficacy standards governing telemedicine (except for radiology and mammography) do not yet exist and the medical community has not extended a blanket endorsement of telemedicine's safety and effectiveness.

**Potential Over Utilization.** There is a risk that telemedicine could be used excessively, that is, without regard to medical necessity. This concern is borne out by some estimates that as much as one fourth to one third of health care expenditures are associated with services or items that may have only marginal benefit. This is not to denigrate the benefits of telemedicine but merely to highlight the concern of insurers that it will be used simply because it is attractive and available.

**System Cost/Benefit.** Savings expected from the use of technologies often fail to materialize or are not applicable to 3rd party payers. For example, one of the savings often attributed to the use of telemedicine is reduced patient travel. However, with the exception of some managed care programs and a few federal and state programs (e.g., Medicaid, DoD, and government correctional facilities), insurers do not incur these costs, and thus, do not benefit from their savings. Additionally, there are concerns about the extent to which the capital costs of a multi-use telemedicine systems should be covered. To what extent will the capital costs of a telemedicine system be recognized as reimbursable? Will payers be expected to cover all infrastructure-related costs, such as hardware, software, and transmission lines, in addition to the associated professional services? Another concern that insurers face is the cost associated with the 2-practitioner model currently used in the telemedicine delivery process.

**Program Integrity.** There is an added risk that providers will try to game the system. Although not a concern unique to telemedicine, it may be more difficult to develop the control mechanisms to monitor potential gaming. For example, providers could bill for certain medical education or other teleconferencing activities as direct patient care. Additional egregious examples would involve kickbacks or referrals to consulting physicians either in the same group practice or a "shell" corporation.

**Impact on Patient Bills.** Potentially, patients may be paying more for a telemedicine consult than they would do under a traditional specialty referral. For example, under most telemedicine programs, the consults involve health care professionals at both ends of the consult. Thus, patients could be paying twice as much for a consult than they would in the absence of telemedicine.

to be sufficient to support some of the high costs of current projects. The challenge still remains to demonstrate the value-add of telemedicine and reduce its costs. The member agencies of the JWGT have engaged in a number of evaluative projects to help demonstrate its value (see Evaluation Chapter).

In particular, HCFA is sponsoring a demonstration to look at payment policy that will be closely

coordinated with ORHP's general evaluation of telemedicine in rural areas and NLM's and AHCPR's activities looking at clinical efficacy.

Additionally, the JWGT will be working with various organizations, such as the National Governors Association, the Western Governors Association, state offices of rural health, HCFA regional offices, and others, to develop evaluation strategies for assessing Medicaid payment policies.

Finally the JWGT plans to work with several managed care plans to evaluate the barriers and

opportunities to the adoption of telemedicine in managed care settings.

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## FOOTNOTES

1. Grigsby, J., Kaehny, M., and Sandberg, E. Effects and Effectiveness of Telemedicine. *Health Care Financing Review*, 1995.
2. 1862(a) (1)(A) of the Social Security Act
3. Tax Equity and Fiscal Responsibility Act of 1982.
4. Grigsby, J.; Sandberg, E.; Kaehny, M.; Kramer, A.; Schlenker, R.; Shaughnessy, P., (1994), "Analysis of Expansion of Access to Care Through Use of Telemedicine and Mobile Health Services, Report 2: Case Studies and Current Status of Telemedicine," 2.7

# TELEMEDICINE REPORT TO CONGRESS

January 31, 1997

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## 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.

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 Tele mammography**

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 tele mammography 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>(1)</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 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>(2)</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>(3)</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>(4)</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 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/nuswpolc.html>

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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 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>(5)</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 standards. It develops test methods for software quality and measurement methods for electronics and manufactured

#### 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."

products, works with integratio issues and the NII, and is in charge of the National Voluntary Laborator Accredita

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

#### 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

issues related to telemedic and have urged medical specialty societies to develop appropria practice parameter The American Academy of Ambulato

Nurses is 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 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.

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## FOOTNOTES

1. The White paper is available on the World Wide Web at: <http://www.fda.gov/cdrh/telemed.html>
2. *The Medical Device Amendments of 1976* (P.L. 94-295) and *the Safe Medical Device Amendments of 1990* (P.L. 181-629).
3. *The Federal Food, Drug, and Cosmetic Act*, Sec. 201. [321 of US Code title 21] (h)
4. (1996). *Regulation of Medical Devices et al.* III-5.
5. House Resolution 3103.

# TELEMEDICINE REPORT TO CONGRESS

January 31, 1997

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## TELECOMMUNICATIONS INFRASTRUCTURE DEVELOPMENT

### A. OVERVIEW

Telecommunications costs are often a major component of a telemedicine project's overall costs. These costs can be very high. Moreover, they can range widely depending on the telemedicine technology approach used. Different telemedicine technologies require different capacities or "bandwidth" of infrastructure, ranging from regular telephone line bandwidth required by low-tech store and forward equipment to expensive broadband infrastructure required by real time full motion television (IATV). As a result, assessing the costs for different combinations of technologies and infrastructures can be a difficult exercise.

Another factor affecting the telecommunications cost and ultimately the cost of the total telemedicine system is the uneven distribution of modern telecommunications infrastructure across the country. In those areas where the information infrastructure is underdeveloped, unreliable, or non-existent, the cost of upgrading the infrastructure can be prohibitive. Yet these same areas would most likely benefit the most from telemedicine services. Rural areas in particular have the least access to high quality and high capacity modern telecommunications infrastructure.

Finally, the fast changing nature of the infrastructure technology itself will dramatically affect the costs to telemedicine. For example, evolving technology such as data compression is likely to significantly change the transmission times and capacity required in the future for sending diagnostic images. In the long run, these advances may decrease overall costs but in the short term it is not as clear whether the costs will increase or decrease.

This chapter looks at the current high costs of the existing information infrastructure and some recent changes in law that may address the problems discussed above.

### B. COST/ BENEFIT TRADE-OFF

The trade-off between potential health benefits in terms of access, efficiency, speed of information transfer and the cost of infrastructure is illustrated in Table 30, which shows the transmission costs for different telecommunications network bandwidths. What does greater bandwidth buy you? Simple "store and forward" equipment transmits recorded images for later review by a health care specialist. This type of consultation might require only standard telephone

**Table 30: Example Transmission Costs for Advanced Infrastructure**

BANDWIDTH	STATE/SITE	DEDICATED LINE	X'ES LATA*	MILES	INSTALL CHRGES	FIXED MNTHLY COST	P C
112 Kbps	MT-Ronan	N	Y	600	200	200	\$0.
ISDN (128Kbps>)	KS-Atwood	N	Y	80	0	545	\$0
T1(1.5 Mbps)	MT-Glendive	Y	N	72	\$1,200	\$1,187	\$0.
	NC-Edenton	Y	N	53	1,250	1,869	
	NE-Callaway	Y	N	63	427	1,917	
ATM (155Mbps)	NC-Chapel Hill (each site)	N	NA	NA	3300	2992	\$0.

Source: ORHP, 1996

LATA\* Local Access Transport Area is a local area telephone service area created by the breakup of AT&T.

lines at normal transmission rates. For example, in transmitting chest x-rays using digitized uncompressed images (2 new films, plus 2 old films for comparison) requires approximately 7 hours over a 14.4 kbps modem, 3.5 hours over a 28.8 kbps modem and only 40 minutes over a more costly ISDN line.

A more interactive store-and-forward system is available through video phones which allow simultaneous transmission of audio and high-resolution still images as the two practitioners examine the patient. Transmission rates of 112Kbps can take place over standard telephone lines. The "interactive" nature of the consultation comes from the simultaneous transmission of audio and visual components. Using ISDN bandwidth of 128 Kbps or higher makes the store and forward transmission even faster, improves image quality and allows for limited quality video conferencing.

T1 (at 1.5 megabits-per-second) capability provides acceptable motion quality and the flexibility to send or receive real-time full motion video and voice among multiple sites, as well as provide data transfer capability in a timely manner consistent with the needs of higher volume, larger providers or health care services. What is gained in speed can be illustrated by the chest x-ray transmission example above which would require 40 minutes over an ISDN line, but only 4 minutes over a T1 line. For applications that need very accurate and detailed imaging, Asynchronous Transfer Mode (ATM) using 155 megabit-per-second transmission can provide very high resolution imaging together with rapid transfer of information. In addition, ATM offers very high resolution videoconferencing capabilities.

It should be noted, however, that advanced infrastructure is usually unavailable or very expensive in rural areas. According to the FCC Telecommunications and Health Care Advisory Committee, "...in most cases the telecommunications bandwidth available to urban health care providers and businesses is not available in rural areas."

**Box 31: The Cost of Infrastructure Accessibility**

An Indian Health Service teleradiology program on the Navajo reservations of Arizona, New Mexico and Utah has six rural health centers linked to six large hospitals. Health care workers can get X-rays read by specialist physicians which reduces improper hospitalizations in an area where 150,000 people are spread across 25,000 square miles and the cost of one air-ambulance transfer runs about \$1,850.

Despite successes, hurdles remain. One is limited infrastructure. Most of the reservations' existing phone infrastructure is antiquated copper lines rather than fiber optic cables. That limitation increases the time needed to transfer teleradiology images. Leasing new phone lines would cut the transmission time down from 15 minutes to a matter of seconds, but it would also add an additional \$36,000 in lease costs.

In several areas of the country, access to modern infrastructure is extremely limited--a number of rural communities

lack rudimentary telecommunications services, relying, for example, on party lines. Where basic telecommunications services for modern healthcare are available, the cost is often four to five times the cost in urban areas, which makes these services unaffordable for rural health providers.

Thus, the telecommunications portion of health costs not only varies with bandwidth requirements but also with accessibility to already existing telecommunications infrastructure. As shown in Box 31, the cost of health care access can be very high in sparsely populated areas, especially where no advanced infrastructure exists.

**Box 32:****Advanced Infrastructure Costs/Benefits**

NTIA's grant to the State of North Carolina helped fund a high speed, 155Mbps emergency telemedicine network with ATM high resolution video & imaging services built upon the state's advanced information infrastructure—the North Carolina Information Highway.

Despite high monthly costs, the system can be highly effective. For example, the very high quality of resolution in the video and imaging services has allowed specialists at Academic Medical Centers to detect subtle problems in rural patients located far away and then quickly redirect treatment as a result of the interpretation of the high resolution images, most likely saving lives.

In other cases where an advanced infrastructure does exist, high resolution live two-way video can provide

great benefits but the monthly infrastructure costs can be high. Box 32 illustrates the trade off between access, efficiency and the cost of using advanced infrastructure. NTIA's grant to the state of North Carolina has helped to develop a high speed, 155Mbps, telemedicine video network with ATM high resolution video services. The state has underwritten the \$4,000-\$6,000 per month total cost of the use of advanced infrastructure.

## C. THE TELECOMMUNICATIONS ACT OF 1996

Important strides in Federal policy toward health care and the information infrastructure were made in the past year. Before 1996, the Telecommunications Act of 1934 articulated in very general terms a national goal of "universal service;" widespread availability of basic communications services at affordable prices, and did not specifically address health care or telemedicine. The link between health care and universal service policy was made explicit in the Telecommunications Act of 1996 which calls for a revision of the universal service system.

The 1996 Telecommunications Act requires that the Federal Communications Commission (FCC) and the states revise the universal service system based on seven principles, including the principle that schools, libraries, and health care providers should have access to advanced telecommunications services. In addition to these broad principles, additional provisions were made that require the FCC to assure that health care providers serving rural areas have access to telecommunications services "necessary for the delivery of health care" at rates that are comparable to those for similar services in urban areas. In accordance with the new law, the FCC convened a Joint Board, made up of Federal and

state communications commissioners, who will make recommendations to the FCC in its revision of the overall universal service policy.

The JWGT has closely tracked the implementation of this legislation through the FCC and has made its expertise available to the Commission on an individual basis. Several members of the Joint Working Group participated in the Advisory Committee on Telecommunications and Health Care which was convened by the FCC's Chairman to assist both the FCC and the Joint Board in implementing the health care provisions of the Telecommunications Act. Those such as Associate Administrator Kathryn Brown of the National Telecommunications and Information Administration, Department of Commerce, testified before the FCC on general universal service revisions. More specifically, the chair of the JWGT group, Dena Puskin, Sc.D. testified before the Commission on how the Joint Board should interpret the provisions of the 1996 Communications Act with respect to health care providers and several members of the working group provided Dr. Puskin with important input to her testimony.

In her testimony, Dr. Puskin outlined her recommendations on issues that are "critical for establishing modern telecommunications services to enhance access to badly needed health care services in rural communities." These issues included: the definition of rural areas, the definition of eligible health care providers, the definition of core services, the definition of advanced services and pricing issues.

The FCC Advisory Committee adopted Dr. Puskin's definition of "rural" areas in its recommendations to the Joint Board as well as some of her other recommendations. The Advisory Committee recommended that "adequate telecommunications infrastructure be made available to rural health care providers. The telecommunication infrastructure must be sufficient to allow eligible healthcare practitioners requesting these services to access a basic set of telemedicine applications necessary for healthcare in rural places." Its recommendation for the basic services to be covered by pricing comparable to that available in urban areas includes:

Internet access (available without long distance charges)

bandwidth up to 1.544 Mbps or equivalent

4.8 kbps for ambulances.

Moreover, the Advisory Committee recommends that universal support ought to be available both to construct the necessary infrastructure to meet these standards and also make rates in rural areas comparable to rates in urban areas. The level of services that are eligible for this support ought to be reevaluated as technology changes.

On November 7, 1996, the Joint Board presented its recommendations to the FCC regarding universal service. While it made specific recommendations for schools and libraries, the Board decided to postpone its recommendations for health care. In brief, the Board requested more detailed information pertaining to health care transmission costs before making a recommendation. These decisions were publicly released for comment and by May 8, 1997, the FCC must act on the recommendations of the Joint Board.

Given that the JWGT's individual members have been deeply involved in the development of the Joint Board's recommendations, the JWGT will continue to closely follow and contribute to the Joint Board's deliberation over the next year.

## **Technology changes**

In addition to legal changes, rapid technology advances in telecommunications have and will continue to decrease the costs of transmission over the long term. Technological advances such as data compression allow services such as imaging to be sent over smaller bandwidth at lower costs. While the FDA allows marketing medical imaging systems that use compression, image compression has not been approved by the American College of Radiology or other standards setting bodies. Therefore, until such time as there is greater consensus on the use of compressed images, the JWGT will continue to base calculations for

transmissions rates on uncompressed images.

## **D. NEXT STEPS**

The current high costs of using the advanced infrastructure can be prohibitive for most rural and some urban healthcare practitioners. Part of the problem lies in the widening gap between those who have access to a modern, reliable information infrastructure and those who do not. The Telecommunications Act of 1996 seeks to increase access to telehealth providers in rural areas by equalizing the costs of telecommunications services in rural and urban areas. With the help of the JWGT committee and the efforts of its individual members, over the next year:

The JWGT will work with the FCC Joint Board and its Telecommunications Advisory Committee to provide further information about telemedicine infrastructure costs and issues.

The Joint Working Group will also work closely with Federal telemedicine grantees who will provide the FCC with detailed information about their infrastructure costs, what they use the infrastructure for, and the comparative value of different bandwidth for telemedicine purposes.

# TELEMEDICINE REPORT TO CONGRESS

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## PRIVACY, SECURITY AND CONFIDENTIALITY IN TELEMEDICINE

### A. OVERVIEW

New technologies have vastly improved the ability to electronically record, store, transfer and share medical data. While these new advances have potential for improving health care delivery, they also create serious questions about who has access to this information and how it is protected. Additionally, this technology is threatened by potential unauthorized intrusion, such as computer hackers who have been known to tap illegally into private information on computer networks. Computer hackers could possibly gain access to and even alter patient records.

Clearly, privacy and security concerns are not unique to telemedicine. Protection of personally identifiable information--whether health information, banking records or employment history data, must be ensured before consumers, patients and other users are willing to participate in electronic commerce or the NII.

However, the challenge for telemedicine policy makers lies in identifying emerging concerns that are unique to telemedicine. Lack of privacy and security standards do play an important role in the legal challenges facing telemedicine (e.g. malpractice) and have profound implications for the acceptance of telemedicine services. This is of particular concern in the use of telemedicine technologies for treating mental illness, substance abuse, and other conditions that carry a social stigma. Given the volume of work on general privacy issues generated by the Federal Government, this chapter will only touch upon some of the general issues related to protecting sensitive patient information as well as potential concerns raised by the use of telemedicine.

**Box 33: Federal Initiatives on Privacy and the NII**

The President's Information Infrastructure Task Force (IIITF) (staffed by the Department of Commerce and other Federal Agencies) has examined privacy issues in the context of its mission to promote the development of the National Information Infrastructure.

The IIITF developed a set of privacy principles to respond to the new information environment. These principles provide guidelines relating to disclosure, data integrity and notice, among other issues, and are intended to be consistent with current international rules.

In addition, the National Telecommunications and Information Administration recently issued a Privacy White Paper that looked in greater detail at a self-regulatory framework that encourages businesses to notify consumers of their intent to use personal information.

### B. GEN PRIV CON AND SECU ISSU

Privacy  
advocates  
and data

experts continue to grapple with the many issues that have emerged as new technology has been employed in the delivery of health care. In dealing with these issues, understanding what these terms

mean is important. According to the National Information Infrastructure Advisory Council, the IITF's private sector advisory group:

**Information Privacy is the ability of an individual to control the use and dissemination of information that relates to himself or herself. Confidentiality is a tool for protecting privacy. Sensitive information is accorded a confidential status that mandates specific controls, including strict limitations on access and disclosure. These controls must be adhered to by those handling the information. Security is all the safeguards in a computer-based information system. Security protects both the system and the information contained within it from unauthorized access and misuse, and accidental damage.<sup>(1)</sup>**

Security also includes training and policies--not just technologies (i.e. fire walls and encryption).

Legal protections for health information generally reside at the state level. While every state has adopted some form of privacy protection, the level of health information protection can vary from state to state. About a dozen states have comprehensive health-care information confidentiality statutes. Two (Montana and Washington) have passed the Uniform Health-Care Information Act of the National Conference of Commissioners on Uniform State Laws, (NCCUSL) (1985). Many state statutes govern specific classes of health information, such as HIV-infection and AIDS patient information, mental health information, and communicable disease information held by public health agencies.

Federal protection of privacy is even more limited than that provided by the states. No explicit right to privacy is guaranteed under the Constitution and privacy protection is derived from case law. The only Federal health record confidentiality law covering the nation is one controlling disclosure of substance abuse patient information, and only specialized substance abuse facilities and units are subject to the law.<sup>(2)</sup> While there are a number of Federal initiatives underway that examine the protection of electronic patient information, there has been little consideration given to privacy issues related specifically to telemedicine (See Box 34).

## C. EMERGING PRIVACY, CONFIDENTIALITY AND SECURITY CONCERNS FOR TELEMEDICINE

Because of the unique combination of patient data, video imaging, and electronic clinical information that is generated between two distant sites during a telemedicine encounter, privacy concerns that normally pertain to patient medical records may be magnified within the telemedicine arena or may be different in character altogether.

### Box 34: Federal Initiatives on Health Care and Patient Privacy

There are several federal initiatives that concern these issues from either a health information perspective or a more general information standpoint.

- **The Department of Health and Human Services** has several initiatives underway relating to the privacy and security of health information through the Interagency Health Privacy Working Group as well as the HHS Data Council and its Privacy Working Group.
- **The National Library of Medicine** has asked the Computer Science and Telecommunications Board of the National Academy of Sciences to examine social and technical means for protecting privacy and security and identify areas for future development and testing. A report is due in early 1997.
- **The Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191, the Kennedy-Kassebaum bill)** directs the Secretary of DHHS to make "detailed recommendations" to Congress "with respect to the privacy of individually identifiable health information."

Telemedicine technology is so new that many new privacy and security issues are just now coming to light. During the past 18 months, the

JWGT has identified a number of situations in which the use of telemedicine could raise concerns about protection of privacy, confidentiality, and security of sensitive patient information. They are:

A lack of uniform confidentiality and privacy legislation at the state level in terms of the transfer of health information in telemedicine encounters (just as there is with respect to health information generally). Since telemedicine consultations can take place over state lines, the potential for confusion over which state's standards should be employed could arise.

A long-distance telemedicine consultation typically involves a clinician-patient session that can be videotaped in its entirety. Thus, the health professional may face his/her own privacy issues under these circumstances. For example, unlike standard medical record documentation in which the practitioner has discretion to selectively record his or her findings, most interactive Telemedicine consultations are recorded in toto. This record is maintained as part of the documentation of the consultation. As a result, practitioners have less discretion to remove sensitive items that they might otherwise not record. From the patient perspective, the patient may not be able to "see" who else is viewing the session along with the clinician on the other side of the long distance consultation.

The use of telemedicine equipment usually adds additional personnel to the typical provider-patient encounter. For instance, a technical outsider, like an engineer, may be privy to the consultation.

From a technical standpoint, there is a higher volume of data and complexity involved in the various communication mediums used during a typical telemedicine consultation. That could make securing the data more problematic.

## **D. NEXT STEPS**

Telemedicine technology brings with it concerns about privacy, security, and confidentiality that go beyond those associated with protecting medical records. Identifying those specific concerns is just now beginning. As a result, a full discussion of these concerns may not be possible until more concrete examples emerge. However, the JWGT, in consultation with the DHHS Privacy Advocate, hopes to examine privacy, security, and confidentiality issues in telemedicine in the coming year. Specifically, the committee hopes to:

Examine the outcome of pilot projects that may provide insights into privacy concerns or identify particular areas that need attention.

Establish a more formal process of examining and identifying those privacy, security and confidentiality issues that uniquely arise out of the telemedicine practice.

Pursue a more permanent linkage with other Federal groups working on privacy issues, particularly the initiatives shown in Box 34.

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## **FOOTNOTES**

1. The National Information Infrastructure Advisory Council, "Common Ground: Fundamental Principles for the National Information Infrastructure," March 1995.
2. 42 U.S.C. secs. 290 dd-3, 290 cc-3(1988). The Federal Privacy Act of 1974, 5 U.S.C. Section 552 a(1988) protects individuals from nonconsensual government disclosure of confidential information. The Act prohibits Federal agencies, including Federal hospitals from disclosing information contained in a system of records except under prescribed circumstances.

# TELEMEDICINE REPORT TO CONGRESS

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## CONCLUSION

This report provides a snapshot of the Federal government's activities in the area of telemedicine. Telemedicine, in one form or another, has actually been practiced for over thirty years. At the most simple level, a nurse providing clinical advice over the telephone is telemedicine. The focus of the most recent activity, however, has been on telemedicine applications that generally employ advanced image as well as audio capabilities. These technologies can range from high resolution still images (e.g., x-rays) to sophisticated interactive teleconferencing systems.

Although interest and investment in these advanced systems is rapidly growing, significant skepticism about telemedicine remains. This skepticism is fueled by concerns about the current low use of telemedicine systems and about continued sustainability once Federal, state, or private subsidies disappear. At the heart of much of this concern is uncertainty as to what the Federal government might do or not do to advance telemedicine.

It is important to remember, however, that telemedicine and the technology associated with it, is fast changing and still in its early development stages. Telemedicine is a rapidly evolving field, requiring flexibility and creativity to respond to its challenges. Moreover, telemedicine encompasses many legal, technical and political issues that must be resolved before it can proliferate. Thus, it will become all the more critical that the Federal government have a vehicle for coordinating its telemedicine policies and programs. The JWGT provides an important forum to accomplish this task. However, even though the JWGT will undertake to support the cost-effective deployment of telemedicine, Federal government agencies cannot resolve all the issues discussed in this report, alone. Congress, the states, health professionals and associations, and the private sector must come together to make telemedicine a viable health care delivery option for the United States. The following discussion outlines areas for further action over the coming year but should be viewed mainly as a work-in-progress.

## A. INVENTORY

As a beginning step in its evaluation of telemedicine, the JWGT created an inventory of Federal telemedicine activities. The Telemedicine Gateway should be viewed as a prototype that demonstrates the usefulness of using the World Wide Web for maintaining distributed data bases across Federal agencies. The basic design of the inventory could be very useful to other initiatives that need to be tracked across Federal agencies. The inventory will undergo further refinement and updating throughout the coming year.

## B. EVALUATION

Much has been written about the barriers to telemedicine and the policies and programs needed to overcome those barriers. Yet, these writings are generally more likely to agree on the nature of the problems than on the solutions. As noted by the Institute of Medicine (IOM) and by others, the lack of quality, scientific evaluations is a major barrier to the adoption of telemedicine. The JWGT has undertaken a number of actions to stimulate the development of such studies. Last winter, it published an evaluation framework that outlined the major questions that needed to be answered in order to adequately assess telemedicine. Members of the JWGT played an active role advising the IOM on its telemedicine evaluation and several member agencies have been active in supporting evaluation studies which have been described in earlier chapters. Over the coming year, the JWGT and its member agencies will be pursuing the following activities to promote better knowledge about what works and what does not in telemedicine.

**Uniform Evaluation Tool Development.** Building upon its previous study with Abt Associates and the evaluation frameworks of both the JWGT and the IOM, the Office of Rural Health Policy has awarded a grant to the Telemedicine Research Center to develop and evaluate instruments for creating a common data set for application across all agencies. Emphasis will be on collecting common data elements on clinical encounters, costs, and the structure of telemedicine provider organizations, wherever possible. The instruments will be first used in ORHP's 20 demonstration projects. The ORHP efforts will be closely coordinated with those of other JWGT agencies, including the NLM and the Health Care Financing Administration (HCFA). The National Telecommunications and Information Administration and the Rural Utilities Service are also coordinating their evaluation efforts with other agencies through the JWGT. It is hoped that this effort will result in data collection tools that would allow for analyses of data across projects.

**Evaluation of Medicaid Telemedicine Programs.** Currently, 10 states offer some telemedicine coverage under their Medicaid programs, but there is no general evaluation effort or opportunity for them to share their experiences, successes, and failures. The JWGT will assess the current level of evaluation activity in the Medicaid program and work with selected states to promote better evaluation. In particular, the JWGT will work with HCFA and ORHP to develop strategies for using state offices of rural health and HCFA regional offices to develop an ongoing mechanism to track Medicaid activities.

**Evaluation of Telemedicine in Managed Care Settings.** Evaluation studies of telemedicine need to be expanded to managed care settings, and in particular, to rural managed care settings. Currently, there is very little penetration of managed care in rural settings, but several managed care plans, most notably in Minnesota and California, believe that telemedicine might provide a more cost-effective way for the plans to reach rural communities with needed services. A question to examine is whether telemedicine technologies will be beneficial to rural communities in the long-run through the provision of specialty care that would otherwise not be available, or will they result in reduced access and availability of care because specialists are no longer visiting these communities to provide care? The JWGT will be coordinating efforts among the agencies to develop some specific evaluations of telemedicine in managed care settings.

**Quality and Efficacy of Care.** Very little current research systematically evaluates the quality and efficacy of telemedicine services. This is a very complicated area of research that needs to be pursued over the next two years if we are to be credible leaders in telemedicine. DoD and the Agency for Health Care Policy and Research (AHCPR) are working together to develop strategies for assessing the clinical efficacy of telemedicine for specific specialty applications. This work may serve as a foundation for other agencies to build upon. State-funded initiatives are also beginning to establish research and demonstration efforts to assess the clinical efficacy of telemedicine services provided in different specialties. The JWGT plans to actively broker partnerships between these state and Federal efforts.

**Evaluation of Telemedicine in Post-Acute Care (Home and Long-Term Care) and in Non-Health Care Settings.** Based on phone inquiries from the health care industry, this is clearly a priority area. One study in Ohio suggests that over 30 percent of emergency hospital readmissions of Medicaid patients from nursing homes might be prevented by timely teleconsulting triage with the patient's primary care practitioners. The JWGT will work with agencies currently funding projects in post-acute and non-health care settings to develop standard evaluation tools.

## C. STANDARDS/GUIDELINES/PROTOCOLS

The lack of technical, educational, and clinical practice standards, guidelines and protocols in telemedicine can affect the safety and efficacy of telemedicine provision and has been a handicap in developing cost-effective programs. Lack of technical standards can result in equipment that cannot communicate with one another or do not provide adequate images for clinical decision-making. All too often, lack of objective technical advice has led to inappropriate purchases and poorly performing systems that hinder the cost-effective application of telemedicine technologies. One of the most frequent questions posed to Federal agencies is: "Where can I get some objective advice on setting up my system?" 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 and the Department of Commerce's National Institute on Standards and Technology also provides testing.

In the coming year, the JWGT will explore the economic and logistic feasibility of expanding these and similar efforts in the private and public sectors to provide a technical assessment capability of telemedicine technologies that would be available to all Federal agencies and their grantees. In addition, the Working Group will continue to work with the FCC and other appropriate bodies to promote greater uniformity of standards in both telecommunications and telemedicine equipment. In addition, the JWGT will continue to work of the FDA in its activities to develop guidelines for defining its role in the regulation of medical devices. In addition to the standards question, questions of monitoring telecommunications service quality and reliability should be addressed.

Lack of standards or guidelines, however, goes beyond telemedicine equipment to issues of guidelines for clinical training and practice. With the exception of guidelines for radiology, there are no specialty-generated standards, protocols or guidelines for providing services through telemedicine. Several groups, however, are in the process of generating such guidelines. For example, the American Academy of Ambulatory Care Nurses is developing practice standards for telephone-based nursing practice. The American Nurses Association is also in the process of developing general standards and guidelines for professional nurses practicing telehealth. Over the next 12 months, the JWGT will be working with Federal agencies, specialty associations, and industry groups to support the development of an agenda for establishing standards or guidelines for telemedicine.

## **D. PRIVACY AND SECURITY**

Although broader than telemedicine, concerns about the lack of privacy and security standards impact several of the legal challenges facing telemedicine (e.g., malpractice) and have profound implications for the acceptance of telemedicine services. This is particularly of concern in the use of telemedicine technologies for treating mental illness, substance abuse, and other conditions that carry a social stigma. Although issues of privacy and security in telemedicine have much in common with those regarding medical records, the use of live, interactive video introduces certain technical dimensions that must be very carefully evaluated. For example, maintenance of secure transmission lines is critical. Moreover, unlike standard medical record documentation, in which the practitioner has discretion to selectively record his or her findings, most interactive telemedicine consultations are recorded in toto. This record usually is maintained as part of the documentation of the consultation. Practitioners have less discretion to remove sensitive items that they might otherwise not record. The JWGT will provide assistance in addressing these and other related issues in the context of the broader privacy initiatives of HHS's Privacy Advocate and its Data Council. The Working Group will bring in representatives from various consumer and professional groups to discuss their views on privacy and security issues in telemedicine. Finally, it will examine available results from various demonstrations and pilot projects that may provide insights into privacy concerns in telemedicine and compile its results in a briefing paper.

## **E. LICENSURE AND CREDENTIALING**

This report contains a full discussion of the licensure issues raised by telemedicine and highlights several of the options for addressing these issues. The JWGT will follow-up the report by convening interested parties, including representatives from the Federation of State Medical Boards, the National Council of State Boards of Nursing, the AMA, the Center for Telemedicine Law, the Western Governors Association and the National Governors Association, to explore next steps, including the development of regional compacts or agreements, to ease the licensure barriers between states. In addition, the JWGT will convene several of the specialty associations and credentialing bodies (e.g., Joint Commission on Accreditation of Healthcare Organizations, AMA, APA, ANA) to explore issues in credentialing of health professionals in telemedicine.

## **F. TELECOMMUNICATIONS INFRASTRUCTURE DEVELOPMENT**

The current high costs of using advanced telemedicine applications can be prohibitive in many areas of the nation because of the high transmission costs. Part of the problem lies in the widening gap between those who have access to modern telecommunications systems and those who do not. The Telecommunications Act of 1996 seeks to ameliorate the inequity between the telecommunications infrastructure "haves and have nots." The JWGT and its members will be working with the FCC over the coming 6 months to assist in developing the necessary information to allow the agency to make decisions that would significantly assist rural and urban underserved health care providers obtain access to affordable advanced telecommunications services that support telemedicine applications.

## **G. TELEHEALTH**

Although primarily focused on telemedicine in its first year, the interests of the JWGT go beyond telemedicine to encompass several aspects of telehealth. The terms telemedicine and telehealth are often confused and used interchangeably. Telemedicine is the use of telecommunications and information technologies for the provision and support of clinical care to individuals at a distance and the transmission of information needed to provide that care. Telehealth includes clinical care but additionally encompasses the related areas of health professionals education, consumer health education, public health, research, and administration of health services. The JWGT is particularly interested in addressing the opportunities for distance learning in health care delivery settings for both health professionals and patients. Moreover, the global implications of telehealth are of increasing concern to the group. As the activities of the Working Group progress over the coming months, more and more attention will be paid to the broader applications inherent in telehealth.

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## The Joint Working Group on Telemedicine

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## APPENDIX B: Telemedicine Funding for JWGT Projects

### Estimated Investment of Federal Agencies in Telemedicine

Name	1994	1995	1996	Total
AHCPR (HHS)	0	\$370,563	\$506,310	\$876,873
ARC	\$486,079	416375	\$187,706	\$1.09 million
DoD	N/A	N/A	N/A	N/A
DOJ	0	\$3.2 million	0	\$3.2 million
HCFA (HHS)	\$4.03 million	\$524,188	\$3.5 million	\$ 8.9 million
IHS (HHS)	N/A	N/A	N/A	N/A
NASA	N/A	N/A	N/A	N/A
NLM (HHS)	\$6.4 million	\$9.7 million	\$13.5 million	\$29.6 million
NTIA (DOC)	\$4.6 million	\$4.7 million	\$3.6 million	\$12.9 million
ORHP (HHS)	\$6.9 million	\$7.6 million	\$10.1 million	\$24.6 million
RUS (USDA)	\$3.05 million	\$2.8 million	\$2.5 million	\$8.35 million
VA	N/A	N/A	N/A	\$100 million

Source: JWGT members

NOTE: The material submitted in this chart was supplied by JWGT participating agencies. The figures represent agency estimates on telemedicine funding and are compiled differently from agency to agency. In some instances, it has been difficult to separate out telemedicine from other expenditures. Therefore, the figures do not necessarily always represent telemedicine as defined in this report. For example, some include activities related to informatics, research and distance learning.



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## APPENDIX E

### World Wide Web Address References for Background Papers and Materials

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- For general information on the Office of Rural Health Policy, contact:

<http://www.nal.usda.gov/ric/richs/orhp2.htm>

- The ORHP/Abt Survey is available at:

<http://www.hrsa.dhhs.gov/news.htm>

- General information about the Department of Commerce's National Telecommunications and Information Administration (NTIA) can be found at:

<http://www.ntia.doc.gov>

- "Lessons Learned" NTIA: Telecommunications and Information Infrastructure Assistance Program is available at:

<http://www.ntia.doc.gov/otiahome/tiap/lessons.htm>

- For more information on FDA telemedicine issues, consult the following web sites:

Proposed FDA classification of medical image management devices, including teleradiology/PACS and other products relevant to telemedicine. The summary of the proposed rule published in the Federal Register is:

<http://www.fda.gov/cdrh/fr1202as.html>

The proposed rule itself is available at:

<http://www.fda.gov/cdrh/fr1202af.html>

- Summary of the September 1996 Software Policy Workshop is available at:

<http://www.fda.gov/cdrh/ost/nuswpolc.html>

- The FDA Report "Telemedicine-Related Activities" is available at:

<http://www.fda.gov/cdrh/telemed.html>

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