Report to the Virginia Department of Health on Improvements Needed In Current Telemedicine Initiatives and Opportunities to Enhance Access and Quality

Submitted to VDH
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By

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Center for Health Policy, Research and Ethics

COMMONWEALTH of VIRGINIA

Department of Health

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MEMORANDUM

TO: The Honorable Mark R. Warner and the General Assembly of Virginia

FROM: Robert B. Stroube, M.D., M.P.H.
Commissioner

DATE: October 1, 2002

SUBJECT: *Telemedicine Study Report*

Pursuant to §32.1-19.1 of the Code of Virginia, VDH contracted with George Mason University's (GMU) Center for Health Policy, Research and Ethics to conduct an analysis of federal and state practices related to the management, evaluation and oversight of public Telemedicine/Telehealth (TM/TH) Services in Virginia. Attached is the legislative study report prepared by GMU. If you are in need of further information or have any questions, please do not hesitate to contact me at (804) 786-3561.

Acknowledgements

The following individuals provided information that assisted with the findings and recommendations contained in this report:

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The George Mason University Center for Health Policy, Research & Ethics (CHPRE)[#] supports scholarship and research, policy analysis, policy forums, and leadership training to broaden the nation's options for improving health care. The Center works in a variety of capacities and in partnership with a wide range of private, corporate, academic and governmental entities and professional associations to provide ongoing policy and ethics consultation, research and education.

CHPRE consulted with external reviewers on specific aspects of this report. Acknowledgments include: Carolyn M. Hutcherson, Health Care Specialist at Arendt and Fox Washington, DC. We also gratefully acknowledge contributions from the National Conference of State Legislatures (Tim Henderson, Rachel Morgan, and ofStephanie Norris) for their insights and for sharing a pre-release copy of a report on current and emerging state telemedicine legislation.

Select Sources And References Cited In This Report

In addition to a comprehensive literature review, a variety of sources were contacted or queried for information/data on various topics and activities related to Telemedicine. Among the state and federal agencies and other private and public entities included in the research for this report are the following:

United States Government Agencies, Commissions, Workgroups and Other Entities

Agency for Healthcare Research and Quality (AHRQ)
Assistant Secretary of Planning and Evaluation (ASPE)
Centers for Disease Control (CDC)
Department of Agriculture
Department of Commerce
Department of Defense
Department of Health and Humans Services (DHHS)
Department of Homeland Security
Department of Justice
Department of Veterans Affairs
Federal Communication Commission (FCC)
Federal Trade Commission (FTC)
National Committee on Vital and Health Statistics (NCVHS)
The Institutes of Medicine (IOM)
Joint Working Group on Telehealth (JWGT)
Office for the Advancement of Telehealth (OAT)

Professional Associations, Academic Institutions, and Others

American Academy of Ambulatory Care Nursing
American Academy of Dermatology
American College of Radiology
American Psychiatric Association
American Psychological Association
Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities.
Federation of State Medical Boards
Joint Commission on Accreditation of Healthcare Organizations
Public Health Foundation
National Conference of State Legislatures
The American Nurses Association
The American Telemedicine Association
University of Pittsburgh Medical Center

Commonwealth of Virginia

Commission on Information Management
Department of Information Technology
Department of Medical Assistance Services

Department of Mental Health, Mental Retardation and Substance Abuse Services
Department of Technology Planning
Joint Commission on Health Care
Secretary of Administration
Secretary of Health and Human Services
Virginia Department of Health
Virginia Department of Medical Assistance Services

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1 EXECUTIVE SUMMARY

Pursuant to §32.1-19.1 of the Code of Virginia (Appendix A), the Virginia Department of Health (VDH) contracted with George Mason University's Center for Health Policy, Research and Ethics to conduct an analysis of federal and state practices related to the management, evaluation and oversight of public Telemedicine/Telehealth (TM/TH) Services in Virginia. This report builds on previous reports of TM/TH services in the Commonwealth and addresses items (iii) and (iv) of the statute:

(iii) Recommendations regarding improvements needed in current telemedicine initiatives; and
(iv) Identification of additional opportunities for use of telemedicine to improve access to quality health care and to health professional education for citizens of the Commonwealth.

Specifically, this report methodology involved a number of strategies to identify relevant background issues and questions informing telecommunications and telemedicine/telehealth These approaches included: critical reviews of prior TM/TH studies conducted on behalf of the Commonwealth of Virginia since 1996[1] and analyses of the literature and influential public policy reports on privacy, liability and evaluation (including cost-effectiveness) pertaining to the authorizing legislation[2]. In addition, we explored current and emerging approaches to the evaluation of TM/TH programs based on available data from other states including legislative and strategic planning efforts. At the request of VDH, this report also includes information on recent national, regional and state efforts to increase public health infrastructure and capacity including telecommunication infrastructure. Specifically, the report highlights core public health functions that serve, in part, as a component of the critical infrastructure in support of the Commonwealth's emergency preparedness response capacity. Indeed, the VDH's central role in ensuring core public health functions through its own infrastructure capacity has been recently expanded, in part, in response to its designation on the Southern Governor's Association (SGA) Telehealth/Homeland Security Task Force. Emerging TM/TH challenges include regionalization of public health and service delivery capacity. Regionalization includes new demands that state departments of health including VDH demonstrate their capacity to rapidly leverage existing public health infrastructure including telecommunication and TM/TH to the extent practicable.

Currently, state and local collaboration is evolving to secure critical infrastructure-- including TM/TH networking capacity--as a fundamental component of essential public health services.[3] Secure networks are vital to the support of public health preparedness[4] especially in the face of natural and other disasters including potential biological (viruses, bacteria, or their toxins) or chemical (hazardous materials or other agents) attacks. Assuring network capacity is also basic

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[1] See Appendix B. Table Summary of Telemedicine and Telehealth Studies in Virginia 1996-2001.
[2] See Appendix A. Authorizing Legislation House Joint Resolution (HJR) 210 of the 1998 Session of the General Assembly.
[3] Public Health Functions Steering Committee, http://www.health.gov/phfunctions/public.htm; accessed September 5, 2002.
[4] Core Public Health Functions and Department of Health and Human Services (Draft) Strategic Plan Fiscal Years 2003-2008. http://aspe.hhs.gov/hhsplan/draft accessed September 4, 2002.

to public health data collection, analysis and reporting that underlie the core public health functions[5] (assessment, policy development, and assurance).

Finally, this report discusses legislative initiatives to assure the growth of telemedicine and telehealth services and to assure comprehensive evaluation efforts in Virginia in the future. To this end, the first step towards reframing policy to support a well-developed and accountable TM/TH infrastructure capacity-is a comprehensive strategic planning process. In the face of shifts in national policy and public health goals, the planning process should include leadership representation from each state agency and leverage existing systems including the public health infrastructure to ensure efficient, effective access for public health surveillance as well as preventive and primary health care for the citizens of the Commonwealth of Virginia. Building on recommendations from previous Telemedicine reports (under Governors Allen and Gilmore) and based upon state and national trends, recommendations for Virginia moving forward are as follows:

- Implement a comprehensive and integrated statewide telemedicine/telehealth (TM/TH) infrastructure strategic planning process,
- Establish and communicate specific authorities and particular roles for state agencies, committees, commissions, and work groups with respect to the:
  - *physical infrastructure* (existing telecommunications and health care resources within the state) and,
  - *functional infrastructure* (administrative, bureaucratic, programmatic and political).
- Establish collaborative systems to ensure interoperability and operations among entities with authority and responsibility to process data and information,
- Coordinate processes for data and information collection, management, reporting and dissemination using standardized frameworks and tools appropriate to the task for policy and program planning within each agency, and
- Create a framework for evaluation of future telemedicine/telehealth activities in the Commonwealth using the mechanisms and elements drawn from prior evaluation frameworks described within the current study.

[5] Institutes of Medicine, Future of Public Health. National Academy Press, Washington, D.C. p.141-142.

2 INTRODUCTION

2.1 Authority for the study[6]

Pursuant to (§32.1-19.1 of the Code of Virginia, this report was conducted for the Commissioner of the Virginia Department of Health.

The Code of Virginia states as follows:

The Commissioner shall annually report to the Governor and the General Assembly on the status of telemedicine initiatives by agencies of the Commonwealth. For the purposes of this section, telemedicine shall mean the use of telecommunications technology to deliver health care services and health professional education to sites that are distant from the host site or educator.

The report shall be issued by October 1 of each year and shall include, but not be limited to, (i) a summary of telemedicine initiatives by agencies of the Commonwealth; (ii) an analysis of the cost-effectiveness and medical efficacy of health services provided using telemedicine; (iii) recommendations regarding any improvements needed in current telemedicine initiatives; and (iv) identification of additional opportunities for use of telemedicine to improve access to quality health care and to health professional education for citizens of the Commonwealth.

2.1.1 Report Purpose

This report represents the third in a series of VDH studies that are directly in response to §32.1-19.1. Components (i) and (ii) of the Code were fulfilled in the 2001 study report and those study findings were not expected to have changed significantly in the one year period since that study. Thus, at the request of VDH, the current report primarily explores sections (iii) and (iv) of the Code.[7]

Specifically, the purpose of this report is to:

- Analyze existing evaluation frameworks, identifying elements that can and should be included in a telemedicine program evaluation in the Commonwealth of Virginia, and strategies to improve telemedicine initiatives and access to quality health care and health professional education in the Commonwealth.

[6] Authorizing language from Virginia code, calling for annual telemedicine studies is presented in Appendix A.
[7] Specifically, section (iii) Recommendations regarding any improvements needed in current telemedicine initiatives; and (iv) Identification of additional opportunities for use of telemedicine to improve access to quality health care and to health professional education for citizens of the Commonwealth.

- Analyze emerging policy issues in relevant to Virginia telemedicine/telehealth initiatives, including population demographics, technological advances, and the role of states to ensure public health infrastructure and capacity.

2.1.2 Previous Telemedicine Studies

Since the enactment of the Virginia telemedicine legislation, three Virginia Department of Health (VDH) studies have been completed (including the current report) in response to §32.1-19.1. Several other legislative reports with a primary focus on telemedicine and telehealth TM/TH were also reviewed (see Appendix B). Based on this review, we make note of the following: Since 1996, eight separate entities were charged with conducting one or more of the authorized studies -- either individually or jointly including:

- Commission on Information Management
- Department of Information Technology
- Department of Medical Assistance Services
- Department of Technology Planning
- Joint Commission on Health Care
- Secretary of Administration
- Secretary of Health and Human Services
- Virginia Department of Health

Authorization for reports related to TM/TH included various specific aims and charges in the objectives for each to address a broad range of policy and programmatic concerns. The prior studies covered a broad range of charges including:

- Analysis of the cost-effectiveness of programs (HD 6, 1996)
- Development of policy specifically focused on reimbursement issues (HD 51, 1997)
- Analysis of barriers to implementation of TM in the Commonwealth (HD 31, 1997)
- Study of reimbursement and quality of care issues (HD 48, 1999)
- Evaluation of current reimbursement polices (SD 51, 1999)
- Report on the status of TM initiatives associated with state agencies (SD 18, 2000)
- Establish guidelines for ensuring compatibility among TM equipment (HD 18, 2000)
- Field test a data collection instrument for TM/TH program evaluation (SD 28, 2001)

Examined chronologically, the studies tend to build on and are responsive to the prior year's findings and recommendations. As such, they reflect an ad hoc rather than a strategic or comprehensive approach to support program planning, policy and decision-making. This is true despite the broad range of TM/TH legislative, regulatory, economic, and health care policy and service delivery concerns addressed. As a result, the overall impact of establishing a coherent process that builds upon previous years' accomplishments and recommendations is largely unrealized for Virginia's previous TM/TH evaluation efforts.

Looking across the previous studies, there is a lack of continuity in the definition of TM/TH services and programs. For example, previous studies have excluded distance learning despite the fact that the use of TM is widely recognized as a cost-effective technique for distance learning, education and rapid dissemination of information, guidelines, standards and information important in the event of an emergency or disaster (e.g., smallpox detection and differential diagnosis.

The following is a brief summary of Virginia's prior study findings and recommendations:

- **A need to broaden the focus** of studies from "high-end' technology to include less sophisticated and less costly but effective TM/TH applications (HD 6, 1996).
- **Address knowledge/consensus** about the use of technology and those responsible for managing payment (HD 51, 1997).
- **Need to improve utilization of local infrastructure** and coordinate TM/TH service delivery with community services based on local needs to achieve cost-effectiveness (HD 31, 1997).
- **Establish formal roles among providers** at the state and local levels for coordinating TM/TH activities under the leadership of the Commissioner of Health to ensure access to care among medically underserved areas (HD 48, 1999).
- **Evaluate the impact of Medicaid reimbursement policies** on expanding access to health care (DMAS, 1999).
- **Develop a comprehensive data collection** and evaluation instrument (SD 18, 2000).
- **Establish statewide planning and coordination of TM/TH infrastructure** including both the technology and service delivery dimensions (HD 18, 2000).
- **Address the need for overarching strategy to guide services within the Commonwealth;** stakeholders including both public and private sector are viewed as seeking individual and narrowly defined problems; designs of current systems are driven by technology rather than health care needs (DMAS, 2000).
- **Establish a baseline assessment of the telemedicine programs** and initiate a continuous quality improvement and evaluation process; continue the TM Program Working Group at the VDH to direct the continuing TM evaluation including collaboration and development of TM initiatives by agencies of the Commonwealth; ensure the integration of technology; and involve local communities, especially local physicians, in the development of TM programs (SD 28, 2001).

Taken together, these findings point toward the need for a comprehensive approach to address crosscutting issues and emerging TM/TH concerns and to support policy and decision-making in the Commonwealth. Among recommendations put forward, HD 18 (2000) suggested establishing of a broad state-level problem-solving effort to address impediments to TM/TH projects and ensure collaboration across public and private entities. Seven specific recommendations were included in that study, a joint collaboration between the Department of Technology and Planning and the Secretary of Health and Human Services for the Joint Commission on Health Care.

These recommendations aimed to ensure the economic development of TM/TH by establishing a mechanism for strategic planning with broad representation from both private and public sectors, local and state agencies, vendors, and the academic communities to provide input and to advise VDH leadership across a range of technical and service delivery challenges. Select recommendations from previous reports also indicate a need for increased coordination and improvements in the strategic planning process utilized in the Commonwealth:

- develop a comprehensive data collection and evaluation instrument addressing economic, programmatic, and technical dimensions of TM/TH service capacity and delivery,
- increase coordination and collaboration among Virginia's academic institutions, public and private payers and other organizations including State Boards of medicine and nursing to review a broad range of issues,
- expand collaboration among state entities involved in TM/TH such as AHEC and Department of Corrections,
- increase the coordination and compatibility of state agencies including increased role of the Commissioner of Health in monitoring agencies' TM/TH commitment and progress, and
- monitor and evaluate federal and state polices pertaining to TM/TH and ensure consistency through the Joint Commission on Health Care.

Challenges to evaluation of TM/TH in the Commonwealth of Virginia that were presented in prior studies enumerated key barriers to evaluation of Virginia programs. Those that pertain to recommendations put forward in this report include problems associated with:

- low-utilization of TM/TH at this stage in the Commonwealth precludes ability to conduct cost-effectiveness studies,
- onerous data collection,
- differing perspectives of stakeholders on issues impacting TM/TH,
- rapidly changing technology and lack of technology integration,
- inadequate understanding or lack of consensus regarding infrastructure capacity,
- inadequate reimbursement and financing, and

- need for rigorous community needs assessment to include local provider and consumer perspectives regarding specific TM/TH services and delivery.

Another important recommendation that appeared earlier is a call for the State Health Commissioner to play a greater role in monitoring the state's commitment and progress in telemedicine (1999, H.D. 48). Additionally, a number of studies have called for establishing an inter-agency oversight body to develop a sustained data collection and iterative evaluation efforts. This would move the Commonwealth away from the historical, ad-hoc analysis it presently employs to a more systematic, comprehensive approach.

Another observation that pertains to Virginia's TM/TH efforts is the absent linkage to core public health functions. This is in spite of a comprehensive public health infrastructure comprised of a central office located in Richmond, 35 health districts with 119 local health departments that provide links statewide through VDH, and to CDC at the federal level. Existing public health infrastructure should be considered a major component of Virginia's TM/TH system. This is particularly important given evolving state and national efforts to improve emergency preparedness and response:

> "...the major public health challenges since 9/11 were not just clinical, epidemiological, technical, issues. The major challenges were communication. In fact, as we move into the 21st century, communication may well become the central science of public health practice."[8] Edward Baker, MD, MPH, Assistant U.S. Surgeon General

A recent Washington Post article described the premium placed on public health surveillance systems that can generate timely data in the event of any disaster. In recommending an emergency coordination plan, the Metropolitan Washington Council of Governments mapped the complex web of agencies through which information must flow.[9] VDH figures prominently in the schema. It is against the backdrop of Virginia's own experience that local, state, regional and national trends provide an important reference for near term and longer-range planning consideration. As a basis to understand recommendations related to strengthening the performance and capacity of Virginia's public health system in the future, a summary of state and nation trends related to telemedicine objectives, barriers and evaluation approaches is provided in the section that follows.

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[8] Dr. Vincent T. Covello's Keynote Presentation: Communicating Under Fire. NACCHO Annual Conference Keynote Address, July 10-13, 2002.

[9] Spencer Hsu. Emergency Plan for Region Unveiled. Washington Post, Thursday September 12, 2002. Metro Section B 1-2.

3 OVERVIEW OF STATE AND NATIONAL TELEMEDICINE TRENDS (OBJECTIVES, BARRIERS AND EVALUATION)

3.1 Telemedicine Program Objectives

This section introduces trends in TM/TH objectives, barriers and evaluations based on a review of available state and national data. Specific implications for Virginia are addressed subsequently in Section V. of this report. Since its emergence in the early 1970s, telemedicine was meant to address a number of problems related to access and costs of health services, particularly in "geographically disadvantaged areas"[10]. Telemedicine supporters assert its contribution to improving:

- maldistribution of medical resources,
- uneven quality,
- high cost, and
- lack of access to care.

3.1.1 Therefore, the potential benefits frequently sought from Telemedicine programs are:

- reducing inequalities in access to specialist health services and health information, particularly in rural, remote and isolated locations,
- timely and comprehensive transfer and sharing of clinical and patient information,
- supporting, educating and training health workers where they live and work, giving them an incentive to remain working in underserved and isolated areas,
- improving communication and cooperation among health providers and between them and community-based services, and
- cost effective and efficient provision of services in rural areas (e.g., reduced transfers to non-local hospitals, availability of specialist advice and reduced travel for both patients and providers).

Asserting these program objectives and merits, states have begun programs with the assumption that the quality of telemedicine services is considered to be similar to traditional care. However, scientific studies comparing the quality of telemedicine services with traditional care services are still needed. For example, one assumed benefit to telemedicine programs is the expectation that by eliminating the "underuse of care" (one of the three causes of poor quality cited in the 1996

[10] Bashshur, R. L. On the definition and evaluation of telemedicine. Telemed J. 1995 Spring; 1(1):19-30.

IOM report[11]), and by allowing more time to be spent with the patient, telemedicine has the potential to improve the quality of care delivered. However, the increased reliability on technology raises the risk of human mistakes or machine failure, and also impacts provider/patient communication and the nature of the 'doctor-patient' relationship. Thus, studies of program efficiencies and clinical efficacy are needed in order to determine whether in fact, telemedicine services are comparable or advantageous over traditional health service delivery.

Patient and provider satisfaction concerning telemedicine services are well substantiated. In a majority of studies reviewed by HHS in its *2001 Telemedicine Report to Congress*, patient and provider satisfaction was high. For example, provider satisfaction was moderate to high and patient satisfaction (largely attributable to reduced travel time) was high. In some studies, patients identified increased access to specialty care as a benefit of telemedicine services (East Carolina University Study 2000). A synopsis of studies reviewed for the DHHS Report to Congress on Telemedicine is contained in Appendix C.

Indeed, taking into account all previous studies, an ASPE/Lewin Report on Telemedicine (2000)[12] noted that, despite some study limitations (e.g. small sample sizes), existing research has established that patient satisfaction with telemedicine has been demonstrated to be high, therefore: "Resources for future evaluations may be better allocated to areas of higher priority".

While positive data about access and patient and provider satisfaction have been recognized, there remains a lack of studies and/or data to demonstrate cost-savings asserted to be associated with telemedicine. Department of Justice telehealth programs are the only programs demonstrating documented cost advantages compared to the traditional care delivery. The majority of telemedicine programs, however, have not provided sufficient statistically significant data for a sound cost-benefit analysis, as Whitten et al. (2002)[13] show in an article discussed later in the report.

3.2 Barriers to Implementation and Development of Telemedicine

In reviewing the literature on TM/TH services and oversight agencies work in tracking telemedicine use across states, four factors were regularly cited as barriers to implementation and or program success[14]:

- cost/reimbursement issues,
- licensure,

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[11] Institute of Medicine. Telemedicine: A guide to assessing telecommunications in health care. National Academy Press, Washington, D.C., 271p.

[12] The Lewin Group, Inc. Assessment of Approaches to Evaluating Telemedicine. Final Report, prepared for the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, December 2000. Available on-line at: http://aspe.hhs.gov/search/health/reports/AAET/aaet.htm.

[13] Whitten et al. Systematic review of cost effectiveness studies of telemedicine interventions. (Information in practice). British Medical Journal, June 15, 2002, vol. 324 issue 7351, 1434-1438.

[14] Caryl, Christopher J. Malpractice and Other Legal Issues Preventing the Development of Telemedicine. Journal of Health and Law, vol. 12, 1997/1998, p.173.

- privacy, and
- malpractice liability.

Some federal reports on telemedicine[15] identified a fifth factor, the inadequacy of the telecommunications infrastructure, and high telecommunications costs that are prerequisite to telemedicine program development and to the expansion of telemedicine programs and services.

The literature and especially the Office for the Advancement of Telehealth (OAT) *Telemedicine Report to Congress (2001)* emphasized two issues that were anticipated to affect the development of telemedicine networks in the future:

- an aging population with increasing needs for home health care and chronic disease management, and
- continuous changes in technology, including the migration towards digitization of data and wireless communications, and the significant increase in use of the Internet to provide health information and services (e-health).

As use of technology increases in relation to these issues, the debate surrounding reimbursement, patient privacy, and especially licensure issues, with both interstate and cross-national dimensions will continue.

A third set of emerging issues, likely to lead to policy change in the near future, is the call to use TM/TH for disaster preparedness, education of providers and communities, communications and treatment, with an emphasis on bioterrorism preparedness.

3.2.1 Reimbursement for Telemedicine Services

Reimbursement of telemedicine services is cited by individual authors, professional organizations, and official telemedicine reports as an important barrier to the advancement of telemedicine in the United States. This as recently expanded, payments for telemedicine services under Medicare and Medicaid are still subject to numerous restrictions. At the same time, lacking convincing data about cost savings and improved quality of telemedicine compared to traditional services, private insurers hesitate to offer coverage for services that involves expensive technologies considered unproven and that might lead to increased cost of care if used as an adjunct to existing approaches in service delivery.

[15] Joint Working Group on Telemedicine (U.S. Department of Commerce, U.S. Department of Health and Human Services). Telemedicine Report to Congress. U.S. Department of Commerce; 1997 Jan 31.

3.2.2 Medicare Reimbursement for Telemedicine

The first policy for reimbursement of telemedicine services was included in the Balanced Budget Act (BBA) of 1997 and implemented in January 1999. However, the scope of the legislation was narrow, with several significant limitations[16]:

- coverage for Medicare beneficiaries only; Patients living in Health Professions Shortage Areas (HPSAs) only,
- fee-splitting requirements between the referring and consulting physician (consultant got 75% of the usual fee for the service),
- the person presenting a patient for a telemedicine consult had to be a physician (however, the majority of rural clinics are staffed with LPNs and RNs).

These restrictive conditions resulted in a very low level of claims for reimbursement by Medicare: a total of $20,000 in nearly 2 years.

In December 2000, the U.S. Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement Act of 2000 (BIPA), implemented in October 2001, resulting in an expansion of Medicare coverage. Fee-sharing requirements between the referring and consulting physician were eliminated, as well as the obligation to have a telehealth presenter with the patient at the consultation (as determined by the physician at the distant site).

In terms of eligibility, BIPA expanded the possible locations of the telemedicine patient from HPSAs only—as BBA of 1997 required—to also non-metropolitan statistical areas, and to entities participating in federal telemedicine demonstration projects and receiving HHS grants. BIPA also expanded the services covered—to include office and outpatient visits, individual psychotherapy, medication management, home health care—as well as allowing limited reimbursement for store and forward technologies other than radiology or pathology. The general rule remains that an interactive communication system is needed.

According to the Director of the Office of Telehealth Assessment, important issues not resolved by BIPA include:

- underserved urban areas are not eligible for coverage,
- services for which telemedicine would be suitable (occupational therapy, nutritional counseling), are not covered,
- patients in nursing homes and rehabilitation centers are not eligible for reimbursement, and
- only store and forward technologies that traditionally do not require a face-to-face interaction (e.g. radiology, pathology) are covered.[17]

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[16] Office for the Advancement of Telehealth (Health Resources and Services Administration). 2001 Telemedicine: Report to Congress. U.S. Department of Health and Human Services; 2001 Jan.

[17] Puskin, Dena S. (September 30, 2001). "Telemedicine: Follow the Money" *Online Journal of Issues in Nursing.* Vol. #6 No. #3. Available: http://www.nursingworld.org/ojin/topic16/tpc16_1.htm

3.2.3 Medicaid Reimbursement for Telemedicine Services

While there is no formal federal requirement for covering telemedicine services under Medicaid, states may pursue telemedicine provided services if they consider them a less costly and more efficient alternative to the traditional care delivery system. However, there are other federal regulations that have to be taken into account when analyzing reimbursement for telemedicine, like the requirement that all providers should practice within the scope of their state practice act, which leads the debate towards interstate licensing issues, examined in the next section of this report. For example, teleradiology, due to its prevalent use in many medical practices, is covered by all states *(CMS Medicaid and Telemedicine Fact Sheet 2002)*, albeit with differing policies on the reimbursement of other telemedicine services authorized under Medicaid.

Approximately 20 states currently provide for some reimbursement of telemedicine services under Medicaid programs: Arkansas, California, Georgia, Iowa, Illinois, Kansas, Kentucky, Louisiana, Maine, Minnesota, Montana, Nebraska, North Carolina, North Dakota, Oklahoma, South Dakota, Texas, Utah, Virginia, and West Virginia. Appendix D contains a synopsis of their reimbursement policies. Generally speaking, payments are provided only under the fee-for-service Medicaid plans, and usually at both ends (hub and spoke) of the telemedicine consultation. A majority of states also require interactive communication between patient and provider as a condition for determining whether Medicaid may reimburse the service. While they have the flexibility to pay for additional costs like line-charges, use of equipment, or technical support, a majority of states do not reimburse these expenses.

3.2.4 Private Third-Party Payers

There are several states (e.g. California, Texas and Louisiana) that enacted legislation prohibiting third-party payers (insurers) to reimburse regular, but not telemedicine, services. Currently, there is no reliable national data source on the level of reimbursement of telemedicine services by non-public insurers. OAT, however, in its 2001 *Telemedicine Report to Congress*, mentions several private insurers that provide limited coverage for telemedicine services (e.g., Blue Cross-Blue Shield in Montana and North Dakota, and Blue Cross of California). OAT is also working on a national study to determine the level of private third-party payments received by its grantees. As observed in *Follow the Money*[18], preliminary evidence suggests that "private third-party coverage is broader than documented heretofore."

3.2.5 Reimbursement in Virginia

At both the federal and state levels, lack of financing/reimbursement issues are cited as the most important barrier to expanding telemedicine services. Virginia is one of the states that allow Medicaid reimbursement of telemedicine consults, comparable to reimbursement for traditional

[18] Puskin, Dena S. (September 30, 2001). "Telemedicine: Follow the Money" *Online Journal of Issues in Nursing.* Vol. #6 No. #3. Available: http://www.nursingworld.org/ojin/topic16/tpc16_1.htm

services. However, the number of claims "remains surprisingly low", as the last Virginia Telemedicine Report (2001)[19] notes. More information is needed in order to understand the reasons for the apparent low number of claims. One rationale offered by state officials points toward the evolution of federal procedures for reimbursement. Specifically, prior studies provide descriptive TM/TH utilization data, but do not yet probe underlying issues related to broader cost concerns. For example, in spite of a long-standing legislative interest in cost-benefit and effectiveness analyses, the studies conducted to date provide inadequate information to support such analyses.

Similar to the rest of the nation, private third-party reimbursement represents only a fraction compared with public funding for TM/TH programs in the Commonwealth. For example, under Medicare, reimbursement is limited to certain areas and services. Currently, the Commonwealth of Virginia is somewhat unique in that the majority of telemedicine services and revenue streams are associated with services provided through the Department of Corrections. As the Commonwealth looks to possibly expand Medicaid managed care contracts, it may wish to monitor closely the experience of other states including California, which use an open-panel service provider arrangement.

3.2.6 Licensure

Licensure requirements for health professionals, traditionally a state responsibility, are widely recognized in the literature as a significant barrier to the development of telemedicine. Although in-state TM services are not usually affected, interstate consults raise numerous licensure questions. While the U.S. Congress is empowered to regulate interstate commerce, states have historically regulated professions and activities that affect public health, welfare, and safety.[20] The major debate thus remains a jurisdictional one: *Is the provider "transported" to the patient, or does the patient "travel" to the provider's state during an interstate TM encounter?* In practice, the majority of professional organizations and regulatory bodies generally accept that the medical 'act' takes place at the location of the patient rather than where the provider is located.

Also impacting licensure concerns is the practice of e-commerce, which had established that a transaction takes place at the buyer's location, if the vendor is in a different state[21]. A growing body of judicial decisions seems to support this view. By analogy, in a TM encounter the provider would be considered to be "transported" to the patient's state. If this were true, the provider would need to be licensed to practice within the state, and would be subject to the statutes and regulations of that particular state's jurisdiction. The literature[22] provides no

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[19] Virginia Department of Health. Report to the Governor and General Assembly on Telemedicine Initiatives. Annual Report, FY 2001.

[20] The basis of this power is the Tenth Amendment to the U.S. Constitution that states that the "powers not delegated to the United States by Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people."

[21] Rock, Edward, and Michael Wachter. Fiduciary Duty, Limited Liability, And The Law Of Delaware: Corporate Law As A Facilitator Of Self Governance. Georgia Law Review, vol. 34, Winter 2000, p.529.

[22] Sulentic, Alison M. Crossing Borders: The Licensure of Interstate Telemedicine Practitioners. Journal of Legislation, vol. 25, 1999, 1-20.

evidence of consensus on the application of this doctrine to telemedicine. Additionally, no case law precedents are available. There are, however, emerging regulations and judicial decisions regarding interstate e-commerce, which are likely to be extrapolated in the future to interstate TM consultations. These are discussed in the emerging public health concerns later in this report and the appendix comprising the National Conference of State Legislature's (NCSL) briefing on emerging state telemedicine legislation (Appendix E).

Other factors affecting licensure are reimbursement rules. Published in 1999, the HCFA Medicare TM reimbursement rules allowed TM consultations to be reimbursed by Medicare if the patient lived in rural health professional shortage areas (HPSAs). The amount of reimbursement, however, took into account *not* the patient's location, but the geographical variations in cost of living at the provider's site. That approach suggested that, in fact, HCFA considered that patient is being "transported" to the physician's office. In this case, no additional licensing would be required.

In 1997, the Joint Working Group on Telemedicine suggested seven types of licensure models that can be applied to the interstate TM use. Sulentic groups these models into three principal categories:

I. State independent efforts

A. Exceptions from licensure for limited (occasional) consult with in-state colleagues.

B. Registration of out-of-state licensed providers who want to practice through TM in the second state, on a part-time basis.

C. Endorsement of the provider's license after verifying his/her credentials.

D. Licensing for specific purposes only (e.g. telemedicine).

II. Regional efforts comprising of more states that either recognize each other's licenses by reciprocity, or develop common licensure standards.

III. States cede their authority to regulate health professions and agree to a national system of licensure.

While the option of a federal system of licensure has been discussed, most authors agree that it is not the most viable solution, especially from a political point of view, even though it would help solve one of the most important obstacles to the TM development[23].

Licensure models are summarized in Table 1 based on the 2001 OAT Telemedicine Report to Congress. A listing of select state telemedicine licensure legislation is included in Appendix F.

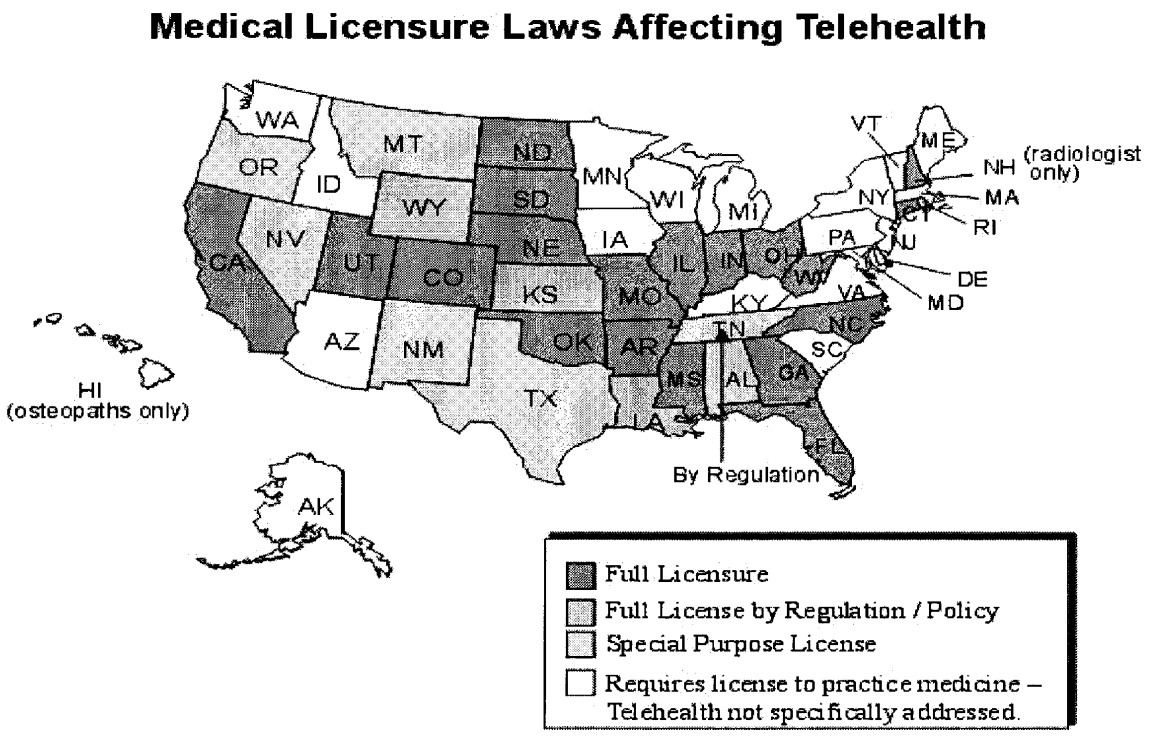
[23] Daley, Heather A. Telemedicine: The Invisible Legal Barriers to the Health Care of the Future. Annuals of Health Law, vol. 9, 2000, p.73.
Darer, Brian. Telemedicine: A State-Based Answer to Health Care In America. Virginia Journal of Law and Technology, vol. 3, Spring 1998, p.4.

TABLE 1: Licensure Models

Consulting Exceptions	A physician who is not licensed in a particular state can practice medicine in that state at the request of and in consultation with a referring physician. Some states permit a specific number of consulting exceptions per year.
Endorsement	State boards can grant licenses to health professionals in other states with equivalent standards. Health professionals must apply for a license by endorsement from each state in which they seek to practice. States may require additional qualifications or documentation.
Reciprocity	Authorities of each state negotiate and enter agreements to recognize licenses issued by the other state without a further review of individual credentials. A license valid in one state would give privileges to practice in all other states with which the home state has agreements.
Mutual Recognition	Mutual recognition is a system in which the licensing authorities voluntarily enter into an agreement to legally accept the policies and processes (licensure) of a licensee's home state. Licensure based on mutual recognition is comprised of three components: a home state, a host state and a harmonization of standards for licensure and professional conduct. The health professional secures a license in his/her own home state and is not required to obtain additional licenses to practice in other states. The nurse licensure compact is based on this model.
Registration	A health professional licensed in one state would inform the authorities of other states that s/he wished to practice part-time there. By registering, the health professional would agree to operate under the legal authority and jurisdiction of the other state.
Limited Licensure	A health professional would have to obtain a license from each state in which s/he practiced but would have the option of obtaining a limited license for the delivery of specific health services under particular circumstances.
National Licensure	A national licensure system could be adopted on the state or national level. A license would be issued based on a universal standard for the practice of health care in the US.
Federal Licensure	Under a Federal licensure system health professionals would be issued one license, valid through the US, by the Federal government.

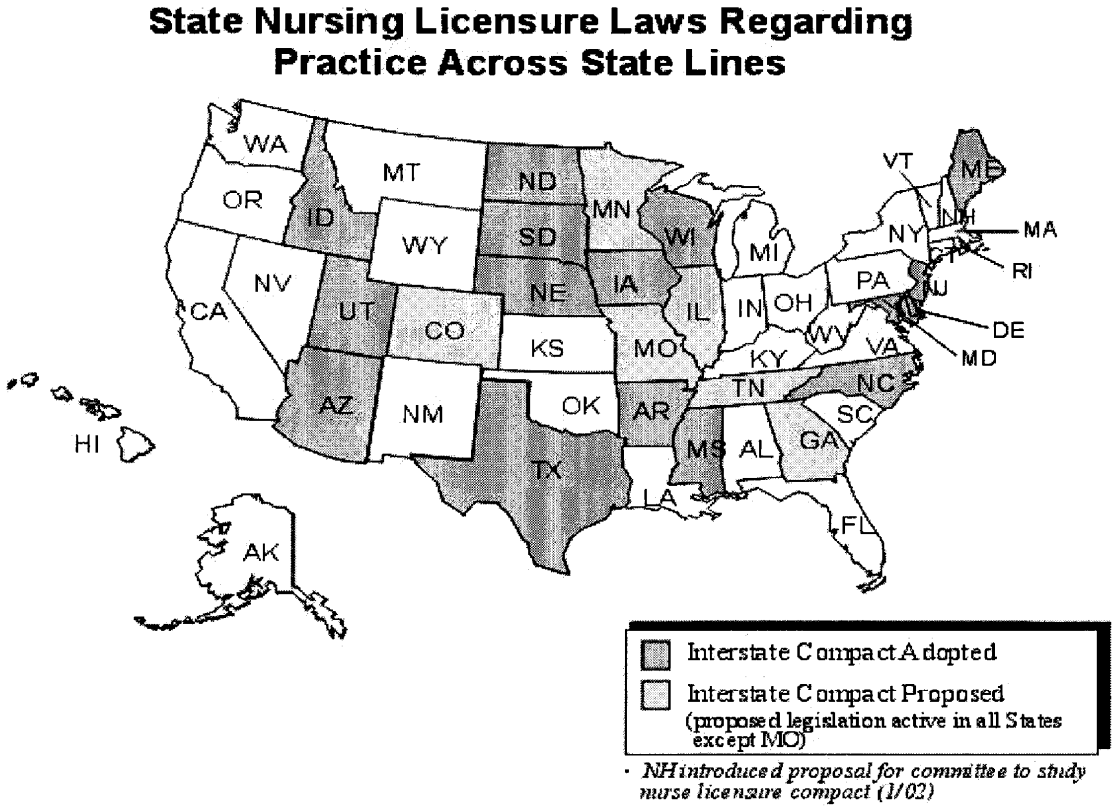
To date, most state licensure efforts reflect unique or independent state legislation, that is to say they do not cross political borders. A Telemedicine Information Exchange survey conducted in 2000 showed that 28 states had no TM specific legislation, 20 implemented restrictive measures that go up to a full licensure requirement, and only three (Alabama, California, and Oregon) had adopted a reciprocity model. More recent data is available from the Center for Telemedicine Law, which mapped state licensure approaches for physicians and nurses (diagram 1 and 2 that follow on the next pages).

Diagram 1.



For TM interstate practice of nurses, the national Council of State Boards of Nursing proposed an innovative resolve: the Interstate Compact, in which participating states would voluntarily agree to allow licensed nurses (both RNs and LPNs) from other states to practice in their state without obtaining a separate license: "license to practice registered nursing issued by a home state to a resident in that state will be recognized by each party state as authorizing a multi-state licensure privilege to practice as a registered nurse in such party state." Sixteen states have adopted the compact. A Center for Telemedicine Law's map, reproduced below, shows the distribution of the states as of mid-2002 that adopted, proposed, or has not yet taken any action on the Interstate Nursing Compact (Diagram 2).

Diagram 2



3.2.7 Conclusions

I. For in-state TM services:

A. Same licensing requirements apply to all health providers as for regular, face-to-face clinical encounters.

II. For interstate TM services:

A. It is accepted that, if not otherwise stated, health providers need to be licensed in the states where the TM patient is located.

As concerns nursing licensure, states are adopting reciprocity rules under the Interstate Nursing Compact. The Commonwealth of Virginia is currently considering its position on the interstate compact. As concerns physicians, most states are requiring full licensure for providers who provide TM services to patients residing in their state. Thus, if inter-state medical services are a part of the telemedicine system, legal experts recommend that providers should avoid liability for illegal practice of medicine by limiting practice to the state wherein they are licensed, or "to become licensed in each state where his TM practice may extend"[24]. Special attention is also focused on the malpractice insurance industry. It is very likely that it will not cover interstate TM

[24] Poe, Kip. Telemedicine Liability: Texas and Other States Delve into the Uncertainties of Health Care Delivery via Advanced Communications Technology. The Review of Litigation, vol. 20, Summer 2001, p. 681.

consultations, especially if physicians are not licensed in the states where their patients are located[25].

The liability insurance industry may also be hesitant to defend insured providers in distant states. Because a patient is sometimes allowed to "shop around" for the most "friendly" jurisdiction in which to file suit, malpractice companies may be reluctant to insure those providers that have multiple licenses or states of practice. To the degree that Virginia practitioners are providing TM services to state residents and to the degree that Virginia Medicaid recipients do not involve inter-state commerce, the implications for Virginia appear to be few. However, growing interest in regional programs including public health service delivery and preparedness concerns (e.g. SGA regional initiative), the inter-state practice is more likely to become a central policy concern. These implications will need to be analyzed, and policy options developed at the state and regional levels.

3.3 Privacy, Security and Confidentiality

Privacy, security and confidentiality concerns remain key issues, but they are not unique to telemedicine. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) not only affects employees' health insurance portability but under the Administrative Simplification (AS) provisions also mandates the development of far reaching national standards for electronic health transactions. These standards include electronic transaction standards for electronic exchange of health information for administrative purposes; standards for the privacy of individually identifiable health information; a national provider identifier; an employer identifier; and secure electronic signatures, among others.[26] The following excerpts from the Report to Congress on Telemedicine provide an overview of key concerns related to telemedicine.

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

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

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

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[25] Caryl, Christopher J. Malpractice and Other Legal Issues Preventing the Development of Telemedicine. Journal of Health and Law, vol. 12, 1997/1998, p.173.

[26] 2001 Report to Congress on Telemedicine. http://telehealth.hrsa.gov/pubs/report2001/main.htm accessed September 16, 2002.

State laws governing health information exhibit wide discrepancies in protection, complexity and coverage as illustrated by a 50-state survey of health privacy statutes that can be found at the Health Privacy Project Web site[27].

While discussion of consumer privacy and the Internet is beyond the scope of this report, it is of growing concern to the public. Georgetown University recently released a report, called the Health Privacy Project, [28] about the practice of privacy protocols on health related web sites. The five major findings are:

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

The FTC offers legislative recommendations to Congress that would set a basic level of privacy protection for all visitors to consumer-oriented commercial Web sites. The legislation would "require all consumer oriented commercial Web sites to the extent already covered by the Children's Online Privacy Protection Act of 1998 (COPPA), to implement the four widely-accepted fair information practice principles." These principles are outlined below.

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

Included in the appendices of this report is a briefing paper that provides greater detail concerning the background of the Health Insurance Portability and Accountability Act (HIPAA).

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[27] Health Privacy Project of the Institute for Health Care Research and Policy at Georgetown University. http://www.healthprivacy.org/resources/statereports/exsum.html, accessed September 16, 2002.

[28] http://ehealth.chcf.org/

3.4 Liability

Malpractice liability is another key factor defining the telemedicine policy landscape. Multi-million dollar judgments awarded by jury trials led to unaffordable hikes in the cost of malpractice insurance, resulting in physicians driven out of practice, and medical centers being closed. For these reasons, the American Medical Association (AMA) made liability reform its "highest priority." Most reform proposals, at the state and federal levels, address jury trials in civil litigation, attempt to limit punitive damages, or change the system altogether (e.g. to a no-fault system in which the injured is compensated by the society through forms of general insurance, rather than by the wrongdoer).

Traditionally, state laws have governed medical malpractice. Several states, including Virginia, have passed tort reforms limiting the amount that can be awarded for "pain and suffering," and lawyers' fees.[29] The AMA-backed legislation recently introduced in the U.S. House of Representatives calls for a $250,000 cap on non-economic damages (i.e., "pain and suffering"), limits attorneys' fess, and allows a three-year statute of limitations.[30]

There is no particular malpractice legislation specifically targeting telemedicine services, such services are currently subject to the same general malpractice legislation within a particular state. As concerns liability matters, the generally held view is that telemedicine is "tool " that helps healthcare professionals to diagnose and treat diseases, rather than a fundamentally different service and is therefore comparable to traditional face-to-face practice[31].

As concerns potential malpractice implications of telemedicine, practitioners should be aware that there are two types of liability issues: related to in-state and inter-state practice. Given current interests in regionalized approaches to practice and policy coupled with advances in technology applications, inter-state practice liability is likely to become increasingly important. The classic four elements of the liability analysis that are entirely applicable to in-state telemedicine practice are: 1.) duty; 2.) breach; 3.) causality; and, 4.) harm. As discussed subsequently, for the inter-state practice, other issues (i.e. licensure) are added to this list.

3.4.1 Duty of Care

Under duty of care, the major question posed is whether a patient-physician relationship was established. In telemedicine, more than one physician or reviewer of the patient's symptoms and data is often involved. Thus, the question is raised: *Which one of the providers or reviewers or consultants has a duty toward the patient?*

The relationship can be clearly established when, for instance, in a TM consultation, the reviewer (consultant) checks patient's medical records, examines the patient, and has the opportunity to

[29] According to AMA, among these states are: California, Colorado, Hawaii, Indiana, Louisiana, New Mexico, Wisconsin, and Rhode Island.

[30] The injured patient would not be able to sue after three years.

[31] Poe, Kip. Telemedicine Liability: Texas and Other States Delve into the Uncertainties of Health Care Delivery via Advanced Communications Technology. The Review of Litigation, vol. 20, Summer 2001, p. 681.

ask questions, then offers advice to the patient or primary provider, usually charging a fee for the service. In other cases however, these distinctions might be blurred. For example, when the patient's information is accumulated on disks or videotapes, and the consultation does not occur "live" (e.g. teleradiology, telepathology), courts are likely to look for a previous contact between the patient and provider before establishing the duty of care.

Kuszler[32] identified two lines of common law cases that address the issue of duty of care and are likely to be used as precedents in any future telemedicine litigation:

- cases that involve phone calls between a patient and physician, resulting in negligent diagnosis and/or advice; and,
- cases in which a secondary or tertiary provider (reviewer) was involved, who not necessarily had a direct contact with the patient, but whose advice was used by the primary physician to make a decision.

To consider that a contract was formed, the patient must not only access the physician directly by phone, but the physician must agree to undertake the care of the patient, and the patient has to rely on that representation. In *Bienz v. Central Suffolk Hospital*, the court found that a physician that provided advice over the phone, on which the patient relied, had a duty of care. On the other side, if the patient does not follow the advice, no patient-provider relationship is established. The same type of analysis would apply to other forms of communication, such as e-mail.

By its nature, TM is more likely to involve multiple health providers (consultants) that review patient's documentation, with or without a direct contact with the patient. This specialty consultation can be divided in two categories:

- *Formal,* when the patient (or only patient's records) is referred to the specialist for a complete evaluation and advice by the primary provider, who usually relies on the specialist's advice when deciding the treatment. This case is commonly viewed as resulting in a patient-specialist relationship, and the specialist usually charges a fee for his/her services. A patient-physician relationship can result even when no contact occurred between the two, if the information obtained was documented by the primary physician, and thus used for future medical decisions and advice *(Bovara v. St. Francis Hospital).*

- *Informal,* when the primary provider just discusses that case with a colleague, frequently without mentioning the patient's name or his entire medical history. The patient may not know about this consultation and is not billed for the service. In these types of cases, courts ruled that no patient-physician relationship existed *(Reynolds v. Decatur Memorial Hospital).*

[32] Kuszler, Patricia C. Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability. American Journal of Law and Medicine, vol. 25, 1999, p.297.

Advances in TM will likely diminish the separation between the formal and informal consults. This shift has the potential to result in more liability questions being raised. For example, it may require the inclusion of secondary and tertiary reviewers of patient's data[33]. Examples like these, with operational and regulatory policy implications, should be monitored and addressed by legal experts and others involved with inter-agency policy and oversight for telemedicine programs and policy activities in the Commonwealth.

3.4.2 Breach Of The Standard Of Care

As a second step in a negligence suit, the patient has to prove that a breach of the standard of care occurred (i.e. he/she received sub-standard care). Historically the 'locality" rule was applied by courts to establish the standard of care for a specific procedure or disease. However, both state regulation and common law precedent have moved toward a more general, statewide or national standard of care. Through a blurring of the barriers of space and time, TM could contribute to the promotion of a unique standard that departs from the more variable "locality rule"[34].

Under the "locality rule," the health provider must follow the standard of care in the local geographical area. The advent of modern communication and transport serves to increase a providers' access to information as well as modern diagnostic and therapy options, which may result in the standard of care being raised.

Virginia is one of the states in which the Supreme Court rejected a nationwide standard of care[35] and emphasis was placed on a standard defined as "the degree of skill and diligence practiced by a reasonably prudent practitioner in the field of practice or specialty in this Commonwealth."

3.4.3 Causality and Harm

In these two last steps in the analysis of negligence, the patient has to prove that a causal relationship exists between the provider's breach of the standard of care, and the harm suffered by the patient. As the other elements of the medical liability doctrine, these steps apply equally to traditional and telemedicine services.

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[33] Kuszler, Patricia C. Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability. American Journal of Law and Medicine, vol. 25, 1999, p.297.
[34] Daley, Heather A. Telemedicine: The Invisible Legal Barriers to the Health Care of the Future. Annuals of Health Law, vol. 9, 2000, p.73.,
[35] Darer, Brian. Telemedicine: A State-Based Answer to Health Care In America. Virginia Journal of Law and Technology, vol. 3, Spring 1998, p.4.

3.4.4 Institutional Liability

In addition to the provider liability, institutional liability in telemedicine should be assessed. First, the liability for any technology failure, probable given a high reliance on complicate equipment in TM, will probably be shared among all parties involved, including the physician and the healthcare facility that owns the equipment[36].

These facilities, as well as health plans,[37] share the liability for the wrongdoing of the providers that work within those facilities, even though they are not the institution's employees. The following two theories of institutional liability are likely to apply to telemedicine:

- *Vicarious liability*, under which the institution is liable for a provider's conduct if the negligent person was its employee or the patient, had reasons to believe so.

- *Direct liability theory*, which includes nondelegable duty, liability for defectively designed programs, and corporate negligence. The latter started to be recognized more frequently in courts, and refers to the hospital's duty to carefully select the providers and monitor them, adopt rules to stimulate a higher quality of care, and maintain the functionality of its facilities and equipment.

3.4.5 Malpractice Liability In Virginia

In Virginia, the recovery resulting form malpractice litigation is subject to a cap of $1,500,000 as of 1999, with an annual increase of $50,000 between 2000 and 2007[38]. This total amount refers only to judgments against medical providers. Punitive damages (e.g. compensation for pain and suffering) are part of that overall cap, and cannot exceed $350,000 from all sources in a single claim (provider and institution).

Moreover, under the sovereign immunity doctrine, "the Commonwealth, its agencies, entities, counties, cities, and towns, are immune from liability for the tortious acts of its agents, servants, and employees." Goodman posits that "physicians and other healthcare providers may be immune from liability for acts of simple negligence, if they are employed by the Commonwealth and meet certain criteria". However, in a case brought before the Supreme Court of Virginia in 1980, *James v. Jane*, medical faculty members of the University of Virginia were not considered to be entitled to immunity for alleged negligence in treatment of patients at U.Va's Medical Center.

The legal implications of the development of telemedicine programs in the Commonwealth of Virginia have to be carefully analyzed, including estimates of the telemedicine impact on the

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[36] Kuszler, Patricia C. Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability. American Journal of Law and Medicine, vol. 25, 1999, p.297.

[37] When not protected by the ERISA's preemption of state laws.

[38] Goodman, Michael L. et al. Damages For Medical Malpractice In Virginia. University of Richmond Law Review, vol. 33, November 1999, p.919.

number of malpractice suits, number of judgments awarded and medical malpractice insurance premiums, as well as the capacity of the system to absorb any negative impacts. A state inter-agency body that includes members representing the Office of the Attorney General would have the adequate expertise to incorporate the legal implications into a broader policy formulation process.

3.4.6 Conclusions

In addition to the liability related to the illegal practice of medicine (i.e. licensure issues), the development of telemedicine is not likely to bring major changes to the way in which courts interpret medical malpractice *(see Malpractice Liability Summary Chart in* Appendix G*)*. However, there are programmatic and regulatory implications of liability in telemedicine, including the potential financial burden of judgments to VDH or telemedicine programs.

The only particular issue that specialists advise about when talking about the specifics of TM is that secondary and tertiary consultants would be more likely to be considered as having a duty of care toward patients, due to the increased amount of patient data they are probable to receive and analyze, and the increased chances of a direct contact with the patient.

Also, by allowing providers to use their TM equipment, medical institutions/facilities are more likely to be perceived as having a tight relationship with those providers and, therefore, to be exposed to vicarious liability for the providers' negligent conduct.

Similar to the face-to-face clinical encounters, the appropriate patient consent must also be obtained, after providing information on the TM procedure itself, advantages and disadvantages, and all other diagnostic and treatment options available. In addition, informed consent should be requested for any videotaping or other form of storage of the patient's information[39].

[39] Volkert, Susan E. Telemedicine: Rx for the Future of Health Care. Michigan Telecommunication and Technology Law Review, vol. 6, 1999/2000, p.147.

4 EVALUATION OF TELEMEDICINE PROGRAMS AND SERVICES

4.1 General Discussion

From the design stage, any telemedicine program should include pre-determined objectives or goals. As the previous reports show, most of the individual telemedicine programs in the Commonwealth of Virginia have clearly stated goals. The evaluation process should assess, at the end of the project or after a specified period of time, if these objectives have been met, what factors fueled successful programs, and what were the major barriers to fulfilling the initial goals. However, overarching objectives used for statewide strategic planning and development of telemedicine have not been formulated, limiting the ability to analyze impact on overall state (not only program) goals.

Most authors writing on telemedicine programs and processes –including the IOM in 1996[40]— maintain that evaluation is an essential part of the process for planning and policy-making. The general consensus includes a recommendation for the inclusion of specific evaluation components at the initial stages of program planning and design. Among the necessary elements required are explicit identification of the evaluation objectives, methodology, data collection techniques and analysis.

Overall, researchers agree that the evaluation process should compare the benefits, costs, and effectiveness of telemedicine with the classic system of providing health services, and assess overall goal attainment. Some authors, however, specify a wide range of non-financial benefits that should also be taken into account, in addition to the classic performance measures. The process of quantifying and gathering data on these non-tangible benefits (i.e., patient and provider preferences) is challenging.

Taking a distinct approach to telemedicine evaluation, Yawn[41] suggests that none of the major existing frameworks or programs look at how to move from "technology assessment to the assessment of telemedicine in the continuum of care." Yawn proposes an alternative framework, based on "the clinical tasks that a physician or other health care provider must do to assess, treat, and follow patients, such as visual, auditory, instrumentation, and palpation tasks." For each of these tasks, the need for settings, tools, and technology would be established, and advantages and disadvantages would be identified, as well as the need for complementary face-to-face encounters, and the integration with traditional services. Finally, the outcomes should be measured by categories of professional tasks rather than for each type of disease or condition.

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[40] Institute of Medicine. Telemedicine: A guide to assessing telecommunications in health care. National Academy Press, Washington, D.C., 271p.

[41] Yawn, Barbara P. Telemedicine: A New Framework for Evaluation. Telemedicine Journal. 2000 Spring; 6(1):55-61.

4.2 Goals

The evaluation process of telemedicine is meant to assess whether services delivered through telemedicine are comparable or better than those delivered through traditional methods. Also, telemedicine is believed to affect the access, quality, and the efficiency of care, and evaluation processes are designed to check if these theories were true, and if there is any further need for investing in expensive telemedicine programs. In a report on telemedicine, the General Accounting Office[42] (1997) emphasized the need for coherent planning strategies at federal and state level to guide investments in new telehealth systems. This lead to numerous planning activities at the OAT and Joint Working Group on Telemedicine (JWGT) level. Guidelines for technology acquisitions were formulated, telemedicine grantees' activities were evaluated, and the experts in the field moved towards consensus in many areas. Some of the lessons learned from the telemedicine programs developed with deferral grants are discussed in this section.

New uses for telehealth are developed and technology evolves rapidly. Thus, the process of formulating new approaches to the evaluation of these new programs and processes in the overall context of telemedicine/telehealth services becomes more important. Any new evaluation framework that will be formulated has to be sufficiently flexible to account for any changes in telemedicine uses or technology.

4.3 Challenges to Evaluation of Telemedicine Programs and Services

Key challenges to telemedicine evaluation as identified by McIntosh and Cairns[43], ASPE/Lewin[44], and Whitten[45] include:

- constantly changing technologies which can make the evaluations unusable in a short period of time, as key telemedicine hardware and software move from being state-of-the-art to being out-of-date,
- multiple uses of a telemedicine system and joint costs, which are difficult to separate for each type of service. Telemedicine uses a group of diverse technologies, each with various applications, and the complexity of these systems must be taken into account,
- inadequate (small) sample sizes, due to a small number of identical services at each site,
- other methodological limitations, including the inappropriateness of the conventional techniques of economic evaluation, the short period of time since most of the

[42] U.S. General Accounting Office. Telemedicine: Federal Strategy Is Needed to Guide Investments. Washington, D.C.: U.S. General Accounting Office; 1997 Feb.
[43] McIntosh, E. and Cairns, J. A framework for the economic evaluation of telemedicine. J Telemed Telecare. 1997; 3 (3):132-9.
[44] The Lewin Group, Inc. Assessment of Approaches to Evaluating Telemedicine. Final Report, prepared for the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, December 2000. Available on-line at: http://aspe.hhs.gov/search/health/reports/AAET/aaet.htm.
[45] Whitten et al. Systematic review of cost effectiveness studies of telemedicine interventions. (Information in practice). British Medical Journal, June 15, 2002, vol. 324 issue 7351, 1434-1438.

telemedicine programs have been in place, lack of uniform data definitions, collection methods and standards, difficulties in designing randomized clinical trials (lack of comparison groups, not enough cases for randomization),

- difficulty establishing cause and effect between telemedicine and improved patient outcome,
- definition and quantification of benefits, especially of the non-health benefits (e.g. improvements in the process of care, patient and provider satisfaction),
- difficulties in assessing the long-term benefits by extrapolating the results from short-term studies, since the effects of the investment in telemedicine on infrastructure and organizations may change in time, and
- level of analysis issues, this is especially true since the choice of perspectives that might be adopted can vary (e.g. patient, provider, medical institution, third party payer, societal).

4.4 Elements of Proposed Evaluation Frameworks

4.4.1 Overview

There have been numerous frameworks proposed for the evaluation of telemedicine programs and services in recent years. While the most widely accepted standard remains the framework put forward in 1996 by the Institute of Medicine[46], several reports have identified additional elements that might be taken into account in developing an evaluation of telemedicine services. This section discusses the most significant frameworks published since 1995, includes elements of cost-benefit analyses, highlights outcomes to be measured and questions to be asked, and identifies lessons learned from the HHS grantees about the planning and implementation of telemedicine programs.

4.4.2 The Joint Commission Framework

Initiated in 1995, the Joint Working Group on Telemedicine (JWGT) brought together representatives from Federal departments and agencies involved in telemedicine activities. The JWGT is charged with assessing the role of the federal government in telemedicine and coordinating these activities across cabinet agencies. A list of the entities represented in JWGT is attached in Appendix H.

[46] Institute of Medicine. Telemedicine: A guide to assessing telecommunications in health care. National Academy Press, Washington, D.C., 271p.

To provide an outline for sharing information across various projects and studies, JWGT identified six main domains that any telemedicine evaluation should address, later used to develop the IOM telemedicine evaluation framework:

- **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?[47]

4.4.3 The Institute of Medicine Framework (1996)

At the initiative of the National Library of Medicine, IOM was commissioned to develop a broad framework for evaluating clinical telemedicine. The report is structured around five principal outcome measures: the quality, accessibility, cost, and acceptability of telemedicine care to patients and to providers. It also mentions four principles at the origin of the evaluation framework:

- evaluation should be an integral part of program design, implementation, and redesign (if necessary),
- complex process aimed at building useful knowledge for decision-makers,
- compares the costs and benefits of telemedicine with those of traditional medical practice, and
- identifies practical and economical ways to achieve results.

Based on these principles, researchers developed six steps for evaluation planning:

- establish objectives for evaluation,
- select the applications to be evaluated, and prioritize them,
- ensure that the evaluation is feasible (i.e. adequate funding and personnel cooperation is available),

[47] 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.

- identify specifically the subject of the evaluation, alternatives used for comparison, outcome measures, and time interval,
- specify the hypothesized relationships between causes and effects, and how these relationships can be changed by other factors, and
- develop an accurate research and analysis plan.

Then, the report outlines the elements of a telemedicine clinical evaluation plan, and compiles a list of comprehensive questions that should be taken into account when evaluating telemedicine. Questions were grouped into four categories, each targeting a specific type of outcome: *quality, accessibility, cost, and acceptability of telemedicine*. The complete list of IOM evaluation questions is presented in Appendix I.

4.4.3.1 IOM - Elements of an Evaluation Plan

The following is a list of the project description and research to be addressed by the evaluation:

- **Strategic objectives**: how the project is intended to serve the sponsor or parent organization's purposes.
- **Clinical objectives**: how the telemedicine project is intended to affect individual or population health by changing the quality, accessibility, or cost of care.
- **Business plan or project management plan**: a formal statement of how the evaluation will help decision-makers judge whether and when the application will be a financially and otherwise sustainable enterprise or, less formally, what the project's management, work plan, schedule, and budget will be.
- **Level and perspective of evaluation**: whether the focus of the research question(s) and objectives is clinical, institutional, societal, or some combination.
- **Research design and analysis plan**: the strategy and steps for developing valid comparative information and analyzing it.
- **Experimental and comparison groups**: characteristics of (a) the group or groups that will be involved in testing the target telemedicine application and (b) the group or groups that will receive alternative services for purposes of comparison.
- **Technical, clinical, and administrative processes**: as planned and actually implemented, the communications and information systems, the methods for providing medical care, and the supportive organizational processes.
- **Measurable outcomes**: the variables and the data to be collected to determine whether the project is meeting its clinical and strategic objectives.
- **Sensitivity analysis**: the inclusion of techniques to assess to what extent conclusions may change if assumptions or values of key variables changed.
- **Documentation**: the explicit reporting of the methods employed in the evaluation and the findings so that others can determine how the results were established.

IOM researchers also listed desirable attributes of the telemedicine evaluation criteria:

- **Reliability/Reproducibility** – repeated use of the instrument leads to similar results,
- **Validity** – the instrument accurately measures the qualities or characteristics it was intended to measure,
- **Responsiveness** – it detects major differences in outcomes across evaluation groups or time periods,
- **Interpretability** – the results of the application are understandable,
- **Feasibility** – the criterion/instrument achieve the desired results within the available resources, and without imposing excessive burdens on those whose cooperation is required for the evaluation,
- **Flexibility** – adaptability to variable evaluation problems and circumstances, and
- **Documentation** – specified user protocols, and summarized or cited evidence of successful use.

4.4.4 The ASPE/Lewin Framework (2000)

Building on the 1996 IOM report framework, the ASPE/Lewin study adds new elements resulting from an extensive literature research and field interviews with telemedicine experts. The two major domains, which experts thought were not fully addressed in the IOM report and needed to be analyzed further, were evaluation properties and impacts, and evaluation methodology issues.

Among the *evaluation properties and impacts*, the report discusses the following issues:

- Access
- Appropriateness of the technology,
- Clinical acceptance,
- Cost and other economic impacts,
- Efficacy and effectiveness,
- Integration into the mainstream of care,.
- Patient satisfaction,
- Safety, and
- Technical properties.

Literature research conducted by Lewin, as well as interviews with experts and site visits emphasized the need to improve the rigor and consistency of telemedicine evaluations, which

suffer from methodological flaws like small samples, imprecise measurement, inadequate or poorly implemented study designs, lack of uniformity in cost analysis.

In an effort to acknowledge the methodological issues that emerged from their analysis, researchers grouped these issues in six categories:

- comparator (control group/intervention),
- focus of evaluation,
- perspective of evaluation,
- randomization,
- technological maturity, and
- time horizon (study duration).

The report concludes with a series of findings/problems and recommendations succinctly presented below:

- Any telemedicine evaluation should at least specify a minimum set of elements (e.g. the purpose, target audience, and the scope or focus of evaluation).
- Patient satisfaction with telemedicine services has been systematically demonstrated to be high, so funds will be better allocated to other areas of research.
- Reimbursement issues (i.e. lack of reimbursement) has been a significant confounder in previous evaluations, since contributed to the underutilization of telemedicine services.
- Research findings are influenced by the economic perspective(s) of the evaluation chosen (e.g. of clinicians, patients, hospitals, payers, or society).
- The evaluation methodology should allow the analysis of any new technologies and applications that are introduced throughout the study period.
- The relationship between the timing of evaluation and the maturity of the telemedicine program should be taken into account.
- Random designs are preferred whenever possible, and control groups are needed.
- Telemedicine must be integrated into existing clinical and administrative functions of the traditional care (e.g. facilities scheduling, records, billing).
- Telemedicine programs should include multi-year business plans and aim at financial independence, which would make their integration into the health care mainstream easier.

4.4.5 National Telecommunications and Information Administration (NTIA) – Technology Opportunities Program Evaluation Framework

Technology Opportunities Program of NTIA provides matching grants to schools, libraries, hospitals, and state and local governments to improve the use of innovative telecommunications and information technologies. The program targets especially inner-city and rural underserved areas. Grant awards can be used for purchasing computer equipment, software or communication services and project evaluation and management. NTIA developed a comprehensive evaluation framework for health services (telemedicine). The steps recommended for the process are:

- describe the project – inputs, activities, outputs, and outcomes;
- define outcomes in measurable terms;
- identify key stakeholders and their interests;
- develop potential evaluation questions;
- prioritize and eliminate questions;
- determine data collection techniques;
- select study groups;
- develop a design matrix;
- develop data collection and analysis matrix; and
- provide (disseminate) information to interested audiences.

4.4.6 The Department of Commerce Telemedicine report to Congress (1997)

The Department of Commerce Telemedicine report to Congress (1997) outlines several valuable lessons learned from the early federally-funded telemedicine projects. This list is an example of how evaluation elements are incorporated in the overall planning and implementation processes, and shows activities employed by the telemedicine programs considered to be successful.

4.4.6.1 In the Pre-planning Phase:

- develop a business plan,
- a thorough needs assessment,
- technology matched to clinical needs,
- a clear understanding of the existing telecom delivery system,
- flexibility -projects must be flexible to adapt to new equipment and technology,
- simplicity,
- human factors - must be useful to practitioners, and

- negotiate telecommunication costs.

4.4.6.2 In the Start-up Phase:

- identify and support a champion,
- communicate a common vision,
- start evaluation right away, and
- foster multiple uses for the system.

4.4.6.3 In the Sustainable Phase:

- maintain training and on-going technical assistance, and
- standards and protocols should work together.

4.5 Economic Evaluations of Telemedicine

4.5.1 Overview

There have been numerous attempts to evaluate the economic component of telemedicine programs and services. However, as a recent study shows, they failed to provide sound "evidence that telemedicine is a cost-effective means of delivering health care"[48].

In a meta-analysis of studies on the telemedicine cost-benefit data, authors discovered frequent and serious methodological flaws. From 612 peer-reviewed articles on the subject, only 55 presented actual cost benefit data, and only 7 studies tried to explore the level of utilization of telemedicine services to be comparable with the traditional care delivery. "Reported studies are often small in scale, methodologically flawed, and reflect pragmatic evaluations rather than controlled trials", the authors of the article note.

Methodological problems are also emphasized by McIntosh and Cairns (1997), and in the ASPE/Lewin report (2000). Most preeminent among these are: small sample size, lack of uniformity in data definitions, collection, and measurement, significant differences in technologies available at each site, lack of accurate study designs (e.g. no control groups). Identification and quantification of non-tangible benefits like patient or provider satisfaction are also difficult to assess. There is a lack of consensus on the best assessment methods that should be used.

The literature analyzed does not provide a unique framework that can be applied to the Commonwealth; however, key elements that should be considered in a comprehensive statewide framework for the evaluation of telemedicine include intermediary outcomes and safeguards to ensure that methodological requirements are met—i.e. adequate sample size and randomization.

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[48] Whitten P.S., et al. Systematic review of cost effectiveness studies of telemedicine interventions. (Information in practice). British Medical Journal, June 15, 2002, vol. 324 issue 7351, 1434-1438.

4.5.2 Framework/Evaluation questions

A recent report by the U.S. Department of Justice *(National Institute of Justice)* and U.S. Department of Defense, Implementing Telemedicine in Correctional Facilities, provides a model for estimation of costs and savings in telemedicine programs. Based on the experience accumulated from a very successful Telemedicine Demonstration Project, the report outlines a detailed model for estimation of costs and savings in telemedicine. The detailed model was developed for telehealth services in a prison environment, but it can be easily adapted to different types of institutions. Packaged as a series of eight linked Microsoft Excel Spreadsheets, the model allows a comparison between telemedicine services and traditional care. Some of the items included in the cost-benefit analysis are listed below:

- cost of facility modifications needed for the equipment installation,
- acquisition costs of the telemedicine system, network, and communication equipment,
- training costs,
- costs to operate and maintain the TM system,
- medical personnel costs,
- medical cost savings that accrue by replacing conventional medical care with telemedicine,
- transportation cost savings, and
- total cost savings, taking into account the payback of TM acquisition costs.

The Department of Veterans Affairs has prepared a telemedicine strategic planning document. The VHA's stated overall telemedicine programs goal is to improve the value of health care provided to veterans.

The department defined a successful telemedicine program as having a strong clinical leadership, well identified needs assessments, strong evaluation and quality components, and flexible, user-friendly technology design. VHA named five *Domains of Health Care* that add up to the total value that telemedicine could bring:

$$Value = \frac{Technical\ Quality + Service\ Satisfaction + Access + Functional\ Status}{Cost}$$

- *Technical Quality* - the successful application and appropriateness of the techniques and technologies to treat medical conditions and the outcomes of these interventions (e.g. clinical efficacy and reliability, technology functionality, easy of operability, compatibility).
- *Cost and/or Price* - the efficient management of appropriated and other funds to operate the VA health care system (e.g. infrastructure, personnel, savings).

- *Service Satisfaction* - the views of veterans and their families about their care (e.g. satisfaction surveys of patients and providers).
- *Access* - the time, distance, and ease of obtaining VA medical care and services (e.g. analyze if the availability of TM increased access through increased convenience, less travel and time spent to access services).
- *Functional Status* - the ability of patients to perform usual and accustomed activities after medical interventions (e.g. established measures of health care function, in comparison with classic medical services).

McIntosh and Cairns proposed a cost-consequence matrix with examples for each category[49]:

Table 2. Cost-consequence Evaluation Matrix

Costs	Benefits
Administrative changes	*Health benefits*
Consultants' time	• Bringing treatment forward in time (e.g. changes in patient management) • Clinical confirmation (second opinion)
Hardware	
Number of referrals	*Non-health benefits*
Running costs (telephone, rent)	• Education • Improve quality of service • Reassurance • Speed of service • Transfer of skills
Software	
Staff changes	
Travel costs	
Treatment costs	

McIntosh and Cairns also defined an evaluation framework comprising nine (9) key questions that should be answered to in the process:

- When should an economic evaluation be carried out?
- Whose perspective should the economic evaluation adopt?
- Does the introduction of telemedicine lead to an increase in the capital costs? If so, are these additional costs offset by lower annual running costs?
- By how much will the number and level of staff increase or decrease? Will the skill mix of staff change? If so, what are the resulting cost implications?
- Will the costs of treatment for certain patient groups be increased or decreased? By how much will patient outcome be improved (if at all)?
- Is there any non-health outcome, which should be included in the evaluation?
- Will consultation and referral patterns change (if so, what are the cost implications)?
- Will activity levels change upon implementation? If so, how will differing levels of throughput affect the cost-effectiveness of the program?

[49] McIntosh, E. and Cairns, J. A framework for the economic evaluation of telemedicine. J Telemed Telecare. 1997; 3(3):132-9.

Bahshur[50] proposed several types of research studies for the economic evaluation of telemedicine:

Table 3. Economic Evaluation of Telemedicine—Research Study Typology

	Biomedical Research	**Health Services Research**
Focus	Clinical performance	Acceptance and effects on heath care delivery
Dimensions	Efficacy Effectiveness Safety	Accessibility
		Quality
		Cost
Concerns	Accuracy Reliability Precision Sensitivity/specificity	Perspectives of client, provider, and society
Methodology	Performance studies	*Field studies*
	Clinical trials	Surveys Field observations
		Experimental studies
		Controlled Quasi-experiments

Bahshur also provided examples of *intermediate* outcomes, important and often cost-saving domains typically overlooked in evaluation studies, to be assessed in telemedicine evaluation:

Table 4. Intermediate Outcomes For Consideration in Evaluation Studies

Health care delivery	*Outcomes*
Content of care	Diagnosis, treatment, follow-up, prevention
Process of care	Scheduling, waiting time, service time, patient flow, case finding
Intermediate outcomes	Outpatient visits, hospital admissions, length of stay
Effects of service on	
Clients	Functional status, satisfaction, access to care, knowledge, attitude
Providers	Patient load, patient mix, satisfaction, knowledge, attitude
Institution	Productivity, efficiency, provider mix
Community at large	Availability of health resources, local economy, cost-sharing with other human services

[50]Bashshur, R. L. On the definition and evaluation of telemedicine. Telemed J. 1995 Spring; 1(1):19-30.

4.6 Federal Standards and Regulations to be Taken into Account when Developing Telemedicine Evaluations

This section includes several mandatory federal standards and regulations that have to be taken into account when developing telemedicine evaluations. Since most of them are fairly new or even emerging, it is difficult to assess whether the telemedicine/telehealth efforts in the Commonwealth of Virginia are in compliance with all of these rules. However, an analysis of how these elements come together to build a federal regulatory framework should be an essential objective of a state-level inter-agency body considering the future of TM/TH in the Commonwealth.

4.6.1 The Food and Drug Administration (FDA) standards and guidelines

FDA historically regulates medical devices intended for human use. However, telemedicine systems and medical software do not require the same degree of regulation. FDA designated the Division of Reproductive, Abdominal, Ear, Nose, and Throat and Radiological Devices to take the leading role in analyzing telemedicine devices. Similarly to the requirements for other FDA-regulated products, the process involves pre-market review, post-market surveillance, and quality systems assessment. Following is a selection of FDA publications that refer to telemedicine issues:

- Guidance for the Submission of Premarket Notification for Medical Image Management Devices (2000),
- Guidance for Industry: Wireless Medical Telemetry Risks and Recommendations (2000),
- FDA Talk Paper: FDA approves first digital mammography system. (2000),
- ODE: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices-, and
- MQSA Regulations relevant to new mammographic modalities are in 21CFR900: Quality Mammography Standards.

4.6.2 Federal Trade Commission (FTC)

FTC is involved in regulating Internet commerce and combating deceptive business practices. Health-related websites that make false health claims represent one of the FTC priorities. The Commonwealth of Virginia may analyze FTC's approach, and propose specific policy actions—legislation, regulations—for the state, to offer supplementary protections to its citizens.

4.6.3 Federal Communication Commission (FCC)

FCC is required by the 1996 Telecommunications Act to stimulate the expansion of advanced communication services to rural health care providers at discounted rates.

In its first order, the FCC decided that rural health care providers, no matter their form of ownership, could obtain advanced communication services at reduced rates (no higher than those charged in the nearest urban area with more than 50,000 people). To accomplish this objective, health care providers and telecommunication services providers are eligible to apply for subsidies.

The FCC order #15 reformed the system, criticized as being too complex, by making long distance carriers eligible for subsidies, eliminating bandwidth and quantity limits, adapting the entire process to the realities in the field, changing the discount calculation and making the application procedure smoother.

In 2000, FCC (through the Rural Health Care Division of the Universal Service Administrative Company) funded 410 telemedicine health care providers, with subsidies totaling $6.1 million. Any communication service is eligible for subsidies, regardless of bandwidth (wireless services are included), if it is used for delivering telemedicine services. FCC is currently developing a new standard for wireless communication services.

4.6.4 Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Rules (1996)

This section discussed the four major provisions included in HIPAA, other than the *Privacy* rule, which was presented earlier in this report and highlights the areas relevant for TM/TH programs.

- *Standards for electronic health transactions* - This rule adopts standards for eight electronic transactions and for code sets to be used in those transactions. It also contains requirements concerning the use of these standards by health plans, health care clearinghouses, and health care providers.

According to HHS, these standards are expected to increase the effectiveness and efficiency of the health care industry in general, by simplifying the administration of the system and enabling the efficient electronic transmission of certain health information. The compliance date for this standard is October 16, 2002 (2003 for small health plans). However, through the Administrative Simplification Compliance Act, Congress authorized a one-year extension for all entities, if they submit a compliance plan by October 2002.

- *National Standard Health Care Provider Identifier* - This rule proposes a standard for a national health care provider identifier and requirements concerning its use by health plans, health care clearinghouses, and health care providers. They would use the identifier in connection with certain electronic transactions. In addition to

overcoming communication and coordination difficulties, the use of a standard, unique provider identifier would also enhance HHS ability to eliminate fraud and abuse in health care programs. The national provider identifier (NPI), which would be maintained by HCFA, will be an 8-position alphanumeric identifier.

- *National Employer Identification Standard-* HHS reasoned that, in all cases where information about the employer is transmitted electronically, it would be beneficial to identify the employer using a standard identifier. HHS adopted the Final Rule for this standard in May 2002.
- *Security and Electronic Signature Standards* - This rule proposes standards for the security of individual health information and electronic signature use by health plans, health care clearinghouses, and health care providers. Based on these standards, entities listed above will develop and maintain the security of all electronic individual health information. The electronic signature standard is applicable only with respect to use with the specific transactions defined in HIPAA, and when it has been determined that an electronic signature must be used.

4.6.5 National Committee on Vital and Health Statistics (NCVHS) patient record standards

Under HIPAA, NCVHS was required "to study the issues relates to the adoption of uniform data standards for patient medical record information (PMRI), and the electronic exchange of such information." The first set of recommendations issued by NCVHS in February 2002, refer to PMRI message format standards. NCVHS recommended HL7 as the main PMRI standard, and several standards to be used by specific PMRI market segments: DICOM, NCPDP SCRIPT, and IEEE 1073[51].

4.6.6 The H.323 network communication standard

The H.323 network communication standard provides a foundation for audio, video, and data communications across IP-based networks, including the Internet, and it was recommended by the Southern Governors Association as standard for communication between the member states. H.323 is an umbrella recommendation from the International Telecommunications Union (ITU) that sets standards for multimedia communications over Local Area Networks (LANs) that do not provide a guaranteed Quality of Service (QoS).

The standard is broad in scope and includes stand-alone devices and embedded personal computer technology as well as point-to-point and multipoint conferences. H.323 also addresses call control, multimedia management, and bandwidth management as well as interfaces between LANs and other networks.

[51] HL7 stands for Health Level Seven, NCPDP for the National Council for Prescription Drug Programs, DICOM for Digital Image Communications, and IEEE for the Institute of electrical and Electronic Engineers.

4.6.7 Center for Disease Control (CDC) – the National Electronic Disease Surveillance System (NEDSS)

Initiated in 2001, the NEDSS Base System is required to be implemented in each state. Specific standards will be in place, and the state systems have to be interoperable. HHS, through CDC, provides funds for states to enter into cooperative agreements aimed at implementing NEDSS, with an emphasis on bioterrorism defense. [52]

The NEDSS Base System provides a foundation system for states to enter, update, and analyze demographic and epidemiologic data, on which the individual departments of health can build additional surveillance programs, in accordance to their needs. With a common platform and data standards, NEDSS will allow a rapid detection of disease or bioterrorism attacks, and a rapid response to any public health event.

CDC currently works with state health departments to introduce NEDSS Base Systems, establish demonstration projects, and provide technical assistance. At the same time, CDC is working on developing national data standards for surveillance and reporting, as well as implementation guides.

4.6.8 Federal Legislative Activity- Telemedicine: Bills Proposed/Passed in the U.S. Senate, 107th Congress

In the 107th U.S. Congress, more than 30 bills aimed at telemedicine activities were introduced. While the majority of those initiated in the House are still being analyzed at the committee level, three important bills emerged in the Senate. Using the vehicle of the community health centers reauthorization program (S. 1533), important telehealth provisions already passed the Senate and were sent to the House of Representatives for consideration. Provisions of this bill are succinctly presented below, together with two other emerging Senate bill, intended to improve telemedicine services in rural and underserved populations, and emphasize the need for emergency telehealth services and interconnections, to assure a timely response to any public health emergencies.

Health Care Safety Net Amendments of 2002. ***Telehealth Grant Consolidation Act of 2002*** **(S 1533)** amends the Public Health Service Act to reauthorize and strengthen the health centers program and for other purposes. The bill passed the Senate in April 2002, and was sent to the House of Representatives for consideration.

Subtitle B, the Telehealth Grant Consolidation Act of 2002 - establishes telehealth network and telehealth resource centers grant programs, administered by HHS and OAT. Grants will be awarded for projects that demonstrate how telehealth technologies can be used through telehealth networks in rural areas, frontier communities, and medically underserved areas, and for medically underserved populations, to expand access, improve provider training; and improve the quality of available health information.

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[52] Bioterrorism preparedness is one of the components of the NEDSS program.

The bill also requires the Secretary to establish a telehomecare demonstration project, and make up to five grants to eligible certified home care providers for the provision of telehomecare.

Subtitle C, the Mental Health Services Telehealth Program and Rural Emergency Medical Service Training and Equipment Assistance Program, requires the Secretary to award grants to provide for improved emergency medical services in rural areas through telemedicine, and to establish demonstration projects for the provision of mental health services to special populations, and of education regarding mental illness using telehealth.

The Medicare Telehealth Validation Act of 2002 (S 2750), introduced in July 2002 in the U.S. Senate targets the expansion and improvement of telemedicine services nationwide.

The bill would authorize the HHS Secretary to administer grants to state and local health departments; Indian health facilities; and community, rural and migrant health centers to establish and expand telemedicine networks in rural and underserved areas. In addition, the legislation would establish a task force to identify, monitor and coordinate federal telehealth programs. The task force would analyze the development of telemedicine networks and make recommendations for their improvement.

Section 3 of the bill also establishes a **Grant Program for the Development of Telehealth Networks,** for the purpose of expanding access to health care services for individuals in rural areas and medically underserved areas through the use of telehealth.

The National Emergency Telemedical Communications Act of 2002 (S 2748), introduced in the U.S. Senate in July 2002 would authorize the formation of state and regional emergency telehealth network test beds and, within the Department of Defense, a telehealth task force.

It would also authorize a $275 million pilot program to develop a network of state and regional emergency telemedicine systems to respond to public health emergencies, such as biological and chemical attacks. Under the bill, a task force established by the HHS secretary would monitor the program and make recommendations to improve interoperability and emergency preparedness within the networks.

4.7 Optional (Non-Compulsory) Governmental and Private Standards

This section includes non-compulsory standards, recommended by private or public entities that have implications for TM/TH programs.

4.7.1 Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards for hospitals using telemedicine

JCAHO is an independent, nationally-recognized organization whose accreditation certifies that a hospital meets certain quality criteria. The new telemedicine standards became effective in January 2001. New elements added later address the issue of emergency preparedness and

capacity. JCAHO's standards have to be followed by any service provider –e.g. hospitals—in the state that wants to be accredited by this private body.

4.7.2 HHS, Office for Advancement of Telemedicine - Technology Guidelines for Clinical Services

Technology guidelines provided by the Office for Advancement of Telemedicine are based on the experience of the HHS telemedicine grantees, and list various types of equipment used in telemedicine services, technical specifications, costs, infrastructure requirements, and examples of medical institutions that have used the equipment, with their contact information. Besides equipment, specific methodologies are also outlined for 11 medical specialties:

- Cardiology,
- Dermatology,
- Ear/Nose/Throat,
- Emergency Medicine,
- Gastroenterology,
- Home Health,
- Neurology,
- Oncology,
- Ophthalmology,
- Psychiatry/Psychology - Mental Health/Behavioral Health, and
- Rehabilitation.

4.7.3 Clinical Guidelines

- *Agency for Healthcare Research and Quality* – in cooperation with the American Medical Association and the American Association of Health Plans, sponsors the National Guideline Clearinghouse, which is a compilation of evidence-based clinical guidelines.
- *American Academy of Ambulatory Care Nursing* - Telehealth Nursing Practice Administration & Practice Standards.
- *American Academy of Dermatology* – Guidelines for Telemedicine Dermatology Services.
- *American College of Radiology* - Standard for Teleradiology.
- *American Psychiatric Association* - Resources on Telepsychiatry.

- *American Psychological Association* - Services By Telephone.
- *The American Nurses Association* - Core Principles on Telehealth.
- *The American Telemedicine Association* - Telehomecare Clinical Guidelines.
- *University of Pittsburg Medical Center* - Clinical and Technical Guidelines for Telepathology.

4.7.4 Agency for Healthcare Research and Quality (AHRQ) evaluation of clinical services (cost-benefit analyses) – Evidence Reports

- Telemedicine for the Medicare Population.
- Telemedicine, Supplement: Indirect Home Interventions.

5 STATE AND REGIONAL ISSUES

5.1 Virginia's Interagency Efforts

The Commonwealth of Virginia has a history of collaboration to identify and address complex and overlapping issues including basic authorities and key responsibilities for TM/TH planning, integrating systems, and establishing interoperational networks for service delivery, monitoring, reporting and evaluation. The following agencies have participated on the various efforts in the past related to TM/TH service planning, operations improvement, and cooperation between entities and to work on evaluation for purposes of a legislative report:

- Commission on Information Management,
- Department of Corrections,
- Department of Information Technology,
- Department of Medical Assistance Services,
- Department of Mental Health, Mental Retardation and Substance Abuse Services,
- Department of Technology Planning,
- Joint Commission on Health Care,
- Secretaries of Administration, Health and Human Services, Education and Technology,
- Telecommunications industry, and
- Virginia Department of Health.

Collectively, the Commonwealth's academic medical centers, Agencies and Departments, Secretaries, Commissions, Committees and Boards may provide necessary crosscutting mechanisms to ensure collaboration for establishing physical and functional TM/TH infrastructure responsive to primary medical care as well as preventive and traditionally public health care. Select examples warrant further investigation to identify underlying infrastructure capacity in order to illustrate how well the system can work to address needs of underserved areas in rural Virginia, HIV/AIDS services to individuals within the Department of Corrections, mental health care and related social services, and public health screening, monitoring and reporting. A draft of the soon to be released Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS) report[53] describes a broad range of telepsychiatry related services providing continuity and quality of care to clients in rural areas of Virginia including: patient evaluations, case management, medication management, crisis response, pre-

[53] James S. Reinhard, M.D., Commissioner, Report on the Expanded Use of Telepsychiatry to the Chairmen of the House of Appropriations and Senate Finance Committees , September 30, 2002.

admission, and pre-discharge planning, treatment planning, individual and group therapy, family therapy, mental status evaluations, court commitment hearings, case conferences, family visits, family and consumer support groups, staff training and administrative activities.

Since September 2001, demands have increased in matters related to ensuring the 'dual use' of the public health infrastructure including technical security, compatibility, and redundancy. These assurances call for increased collaboration in order to take advantage of available physical and functional capacity to support core public health functions and emergency preparedness. Previous studies have observed that bureaucratic and other turf issues inhibit optimal system-wide interaction and integration of services. These findings are not unexpected from programs with a primary focus on unique ways of doing business. These consequences become a concern only as Virginia considers how to remove barriers to more effective collaboration in order to meet broad public health access needs and to function well in response to emergencies. Given the shift towards 'dual use' capacity being placed on the public health infrastructure, the current conceptual framework, which includes a prevailing reference to 'hubs' (centralized unique service centers) and 'spokes' (remote recipients of these services), requires a different organizing concept.

5.2 Core Public Health Promotion Issues, Public Health Preparedness and Biodefense

Public health is much better prepared to respond to a bioterrorist threat than a year ago, says a report card released by the American Public Health Association[54]. However, public health remains vulnerable and work on related fronts to date is insufficient to prevent future acts of terrorism and their adverse health consequences. As states address ways to protect citizens from potential further terrorist attacks, public officials are considering the benefits of distributing vaccines. US health officials were expected to issue detailed guidelines Monday for vaccinating the entire US population against smallpox within five days of an outbreak of the disease, according to a report in The Washington Post.[55] In just six months, 35 states and the District of Columbia introduced legislative bills or resolutions based in whole or part on a Model State Emergency Health Powers Act created by the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities. To date, 19 states and D.C. have passed their legislative versions of the Act. The National Conference of State Legislatures (NCSL) released a new Public Health project providing a checklist to states in response to the Act, an initiative to inform state legislators about priority public health issues. The checklist helps legislators review the adequacy of their public health preparedness initiatives. The conceptual link between TM/TH and public health preparedness challenges those unfamiliar with the core public health functions. A key role of VDH includes ensuring the basic public health capacity and functions for the Commonwealth including *assessment* (monitoring and diagnosis), *assurance* (enforce laws and assure workforce) and *policy development* (inform, education and empower communities and mobilize partnerships). Telecommunications and TM/TH are one mechanisms for rapid response and infrastructure capacity building.

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[54] Public Health Preparedness accessed September 23, 2002. http://www.ncsl.org/programs/health/phguide.htm
[55] The Washington Post, September 23, 2002.

In the wake of the September 11, 2001 terrorist attacks, Congress has become responsive to long-standing calls for improving the public health infrastructure, especially for identifying local, state and regional capacity for rapidly respond to disasters--including biological and chemical events. Discussion about basic public health functions and issues has continued throughout the current congressional session (i.e. Healthy People 2020 targeted activities) along with a growing consensus of the need to improve utilization of public health infrastructure and capacity at the local, state, regional and national levels.

Federal legislators have reacted to concerns about public health preparedness, including the capacity to respond to biological and chemical agents, in a number of ways. First, bioterrorism funds were included in emergency spending legislation attached to the FY 2002 defense appropriations act. In addition, funds were appropriated to improve public health response capabilities at all levels of government to help states and communities build a better connected health system and thereby strengthening the ability to respond to an attack[56] (See also Appendix J. Near Term HHS Target Areas). Secretary Thompson's announcement emphasized national funding would be made available as a 'first step' to create/ensure that HHS, state and local governments have the capacity to begin working on building a successful public health infrastructure.

In addition to appropriations efforts, both the U.S. House (H.R. 4061) and the Senate (S. 2054) introduced bills to establish state networks and a national network for tracking of chronic diseases including environmental risk factors. There are minor differences between the two bills. Both call for pilot projects, a commission on nationwide health tracking, and funding beginning in FY 2005 for grants to states to establish state tracking networks. States could use their grant funds to (among other things) "collect data through bio-monitoring and other advanced methods." The bills call for use of existing systems and surveys to the maximum extent practicable. The bills also provide for a nationwide health tracking network, again emphasizing use of existing data sources including NHANES, and require the expansion of bio-monitoring data collected by CDC such that data will be available at the census tract or other appropriate level on a range of environmental exposures including prenatal exposures.[57] Both bills include provisions to:

- upgrade CDC facilities and public laboratories;
- expand the national stockpile of drugs and vaccines, including smallpox vaccines;
- establish an Assistant Secretary for Emergency Preparedness in HHS;
- enhance state and local preparedness including authorizing block grants for states to develop emergency response plans and improve public health departments;

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[56] Federal Funds For Public Health Infrastructure Begins To Flow To States. http://www.seniors.gov/articles/0102/bioterrorism-funds.htm accessed September 4, 2002. See also Appendix J. Near-term HHS Target Areas.

[57] PUBLIC HEALTH GIS NEWS AND INFORMATION September 2002 (No. 48). Page 18.

- encourage development of new medicines for anthrax and smallpox; and
- improve food safety.

5.3 *Improving the Use of Current Infrastructures—Linking Medical and Public Health Capacities*

The previously mentioned Senate and House bioterrorism bills were not the same, so negotiations were underway Spring 2002 to reconcile the two measures. The Senate bill included broader provisions on food safety inspections and agricultural bioterrorism, while the House bill included provisions on protection of drinking water supplies. Bills on other aspects of bioterrorism have also been proposed, particularly in the Senate. A Senate bill has been proposed to among other things authorize funds to improve coordination of disease surveillance and establish a nationwide database of medical formation related to bioterrorism. A bill proposed by Senator Leland (D-GA) would clarify the responsibilities of CDC as opposed to law enforcement agencies when dealing with a public health emergency. Another Senate bill would authorize activities to protect the health and safety of community members and workers in disaster areas. It provides for collection and analysis of environmental exposure data, performing baseline health assessments, and conducting epidemiological studies to determine long term impact. Also, a number of bills have been introduced to address the mental health needs of those impacted by the terrorist attacks. No action has occurred on any of these bills. Finally, a model state emergency health powers act[58], commissioned by CDC and drafted by public health and legal experts outside the agency to assist states in planning for a terrorist attack, has been released. This model law, which states are not required to adopt and that can be tailored to the particular needs of each state, would give states broad power to take action to protect public health in the event of a major bio-terrorist incident[59].

In June, the president signed into law (P.L. 107-188), an anti-bioterrorism bill. This law provides the policy parameters to go along with funds appropriated to fight bioterrorism. It authorizes funding for activities to enhance preparation for public health emergencies including funding for grants to enhance state and local preparedness and antibioterrorism capability. It also expands the national stockpile of medical vaccines and supplies, and authorizes funds to upgrade CDC equipment and facilities, to increase food inspections, to protect the water supply, and to conduct research on anti-microbial resistant pathogens.

The Administration's proposal for a Department of Homeland Security addresses bioterrorism, proposing to move to the new Department some NIH and CDC research activities, management of the national pharmaceutical stockpile, and Department level disaster response responsibilities.

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[58] Speissiger, Lisa and Cheryl Runyon. The Model State Emergency Health Powers Act A Check List of Issues. National Conference of State Legislatures. June 2002.

59 Excerpts are drawn from the August 2002 Report on Legislative Activities National Center for Health Statistics, Office of Planning, Budget and Legislation as cited in PUBLIC HEALTH GIS NEWS AND INFORMATION September 2002 (No. 48) p. 18. http://www.cdc.gov/nchs accessed September 4, 2002.

In House action, the proposed transfer of research activities was scaled back. Even if research activities were to be transferred, there is strong support for contracting back this responsibility to the Department, while maintaining budget control in Homeland Security. Further action on this bill will take place in September.

Additionally, recent legislative activities include the introduction of bills in both the Senate (S. 2054) and the House (H.R. 4061) to establish state networks and a national network for tracking of chronic diseases including environmental risk factors. There are minor differences between the two bills. Both call for pilot projects, a commission on nationwide health tracking, and funding beginning in FY 2005 for grants to states to establish state tracking networks. States could use their grant funds to among other things "collect data through bio-monitoring and other advanced methods." The bills *call for use of existing systems and surveys to the maximum extent practicable* (italics added). The bills also provide for a nationwide health tracking network, again emphasizing use of existing data sources including NHANES, and require the expansion of bio-monitoring data collected by CDC through the states and local health departments such that data will be available at the census tract or other appropriate level on a range of environmental exposures including prenatal exposures. The bills require the Secretary to issue an annual tracking report beginning four years after enactment. The Senate Health, Education, Labor, and Pensions Committee anticipate acting on this bill after the August recess.

5.4 Private and Public Sector Partnerships for Infrastructure Security and Capacity

There emerges from the Congressional debates a need to bring together experts from all fields to assist in mapping a comprehensive and overlapping framework to ensure the physical and functional integrity of the TM/TH infrastructure. Timely, accurate and accessible data and information capable of being shared across federal, state, and local political jurisdictions is fundamental to policy and decision-making. This is true in response to ensuring capabilities across the numerous agencies tasked with ensuring Virginia's TM/TH infrastructure including expanded responsibilities and functions emerging, for example, under the Office of Commonwealth Preparedness[60]. The task at hand will require public private partnering as evidenced in these excerpts from an Environmental Systems Research Institute (ESRI), White Paper, (October 2001)[61]:

> A fundamental component of security is information, and for homeland security this means geographic information...Homeland Security will require managers at all levels of government to develop effective methods to collect, analyze, and share location-based data to do effective planning... [and] The value of building data warehouses for each community as well as obtaining permissions and access to invaluable proprietary data sets cannot be stressed enough. Gathering data to create a [geographic information system] GIS to meet potential emergencies requires an

[60] Homeland Security National Strategy—Virginia State Document. http://www.commonwealthpreparedness.state.va.us/documents/HomelandSecureNatlStrategy.pdf accessed September 4, 2002.

[61] GIS and Homeland Security http://www.esri.com/library/whitepapers/pdfs/homeland_security_wp.pdf accessed September 16, 2002.

immediate and concentrated effort. It is far easier to accomplish this task before an attack or emergency than in its aftermath.

5.5 Opportunities to Improve Access to Quality Care: Emerging State Legislation and Regional Health Emergency Preparation and Response Network

5.5.1 Legislation in Other States

This section addresses potential future public health uses of telemedicine. These are reflected in emerging state legislation and the growing interest in regional planning and service delivery—including dual-use public health response infrastructure to improve the capacity to respond to all public health emergencies and hazards. Emerging State legislation is highlighted, in particular, with respect to TM/TH issues concerning strategic planning, distance learning, delivery systems, e-health, licensing and reimbursement. The role of VDH in supporting current strategic planning for public health infrastructure capacity and service delivery is described prior to introducing recommendations and next steps.

In August 2002, the National Conference of State Legislatures (NCSL) published an updated annual telemedicine and telehealth issue brief (See Appendix E). The issue brief summarizes current and emerging state legislation, which is monitored by the Health Policy Tracking Service. The NCSL TM/TH issue brief provides a picture of current and emerging telehealth and telemedicine issues that State governments are faced with concerning increased use of technology and the long-distance provision of care including:

- **Strategic Planning Initiatives**
  - *Coordinating Council and Distance Education* within the Office of the Governor (Louisiana)
  - *Telehealth Board* (Kentucky) under the Governor's Office of Technology to establish telehealth training centers at the University of Kentucky, University of Louisville, and one each in western and eastern Kentucky and to establish a telehealth network to coordinate with the training centers,
  - *Institute of Technology* (Oklahoma) will develop ways to attract and retain faculty and graduate students at colleges and universities through public-private partnerships,
  - *Telehealth Workgroup* (Florida) has developed a strategic plan for telehealth in collaboration with Departments of Health, County Health Departments, Children's Medical, Nursing, and Other Services to identify resource needs and projects.
- **Distance Learning Programs**: the ability to provide education and rapidly disseminate information about new treatments, alleviates some of the strain caused by

the availability of fewer health professionals in select communities; U.S. Department of Agriculture's (USDA) Rural Utility Service Distance Learning and Telemedicine Program offers loans to operate rural educational or health care facilities.

- **Distance Delivery Services**: several states moved ahead during 2000-2001 with legislation on distant delivery systems including TM/TH services related to:
  - *telepharmacy* (Montana, Texas, Utah);
  - *health screenings, prenatal care, medical and surgical follow-ups* (Texas);
  - *periodic consultation with specialists regarding chronic conditions*(Texas);
  - *triage and pre-transfer arrangements* (Texas);
  - *transmission of diagnostic images or data* (Texas);
  - *behavioral health* (Arizona);
  - *senior care* (Minnesota);
  - *primary care medical services in rural or frontier counties* (Idaho); and
  - *nursing and public health care* (Hawaii).
- **E-Health**: At the national level, a January 2000, Report on the Privacy Policies and Practices of Health Web Sites,[62] provides evidence concerning persistent consumer concerns about patient privacy in electronic exchange of medical information that, in turn, has prompted federal initiatives to regulate e-commerce with implications for providers and consumers. For example, regulations including HHS final rule that adopts standards and code sets for electronic transactions are discussed elsewhere in this report (See Appendix K. HIPAA). At the state level, the Western Governor's Association is sponsoring an 18-month pilot project, the Health Passport Project, to determine if personal electronic data cards, called smart cards, can be used to improve health care and reduce costs. Nevada, North Dakota and Wyoming are participating in a pilot.
- **Licensing**: chief concerns stem from the practice of TM/TH involving multiple jurisdictions across stateliness, wherein it can be unclear which jurisdiction is ranking when services are provided with some sates providing full and unrestricted licenses, while others are considering and issuing limited licenses or national licenses. Since 1994, 24 states have passed licensure laws including Alabama, Florida, Georgia, North Carolina, Mississippi, Tennessee, Texas and West Virginia.

In 1996, the Federation of State Medical Boards (FSMB) adopted model legislation to require physicians engaging in TM across state lines to obtain a special license issued by the state medical boards. Since 1995, six states—Alabama, California, Montana, Oregon, Tennessee and Texas have enacted legislation consistent with the FSMB's model legislation.

[62] The Health Privacy Project of the Institute for Health Care Research and Policy at Georgetown University has compiled a comprehensive 50-state survey of health privacy statutes. A summary of findings is found at the Health Privacy Project Web site at: http://www.healthprivacy.org/resources/statereports/exsum.html.

The American Medical Association (AMA) opposes the model act and called for a resolution requiring "full and unrestricted license' in each state for those 'who wish to regularly practice telemedicine in that state."

North Carolina enacted legislation (SB 2140) that will require any provider who treats a patient via the Internet or a toll-free telephone to obtain a license to practice telemedicine in NC.

- **Reimbursement:** Virginia Medicaid presently requires that a physician or nurse practitioner be at both the hub and spoke sites in order to qualify for reimbursement and will only reimburse for a specific list of 19 billing codes negotiated with three specific sites (UVA, MCV, Appalink) that were identified as part of the telemedicine reimbursement pilot project. DMAS is considering expanding its telemedicine coverage, however, to include what Medicare covers for telemedicine. DMAS is also revising its contracts with Managed Care Organizations to include telemedicine coverage that parallels DMAS coverage for recipients enrolled in fee-for-service and Medallion. See Appendix L for a listing of current DMAS covered services.[63]

According to the NCSL report, 18 states currently allow Medicaid reimbursement of telemedicine services. These states include Arkansas, California, Georgia, Illinois, Kansas, Louisiana, Minnesota, Montana, Nebraska, North Carolina, North Dakota, Oklahoma, South Dakota, Texas, Utah, Virginia, and West Virginia.

5.5.2 Regional Health Emergency Preparation and Response Network

As a member of the Southern Governor's Association (SGA), Virginia is represented by a delegate from VDH on the SGA Telehealth/Homeland Security Task Force. In August of this year, VDH participated in a regional survey supporting the development of a proposal that, aims to establish a network system capacity for the 15-state region. At the time this report was written, a decision on funding for the SGA proposal was still undecided. The select SGA proposal excerpts that follow provide a conceptual framework for designing and implementing an expanded network system supporting TM/TH in the Commonwealth. The system would allow for the rapid and secure dissemination of information on demand during emergency situations and allow participating entities (the SGA member states) to share health information and consultative expertise on an on-going basis.[64] As part of the proposal process, VDH facilitated Virginia's participation in the SGA-sponsored regional survey to assess the current networking capacity. The results identified current linkages including: Health Alert Network (HAN), operational and billable TM/TH systems or sites, and Distance Learning (DL) systems or sites that provide health education.

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[63] Personal correspondence with Jeff Nelson, Department of Medical Assistance Services, September 16, 2002.
[64] Southern Governor's Association. Proposal for a Regional Health Emergency Preparation and Response Network. A Review of Current Information Based on the SGA Survey Data August 9, 2002.

The SGA survey of regional network capacity also served more broadly to identify critical infrastructure capacity including: geographic mapping of state networks that support current as well as planned 2-way video conferencing for HAN and DL and TM/TH communications lines; current HUB locations (origination site that communicates with multiple remote sites); distribution of networking capabilities by state (intra- and inter-state, connectivity on demand, redundancy, and bridging); and identification of "Regional Resource Centers" comprised of medical facilities, governmental entities, private industry, and academia. The specific aims of the SGA proposal are to support the connection of 3 National Resource Centers and 36 Regional Resource Centers to the Regional Network. In addition, the Regional Network will make connected Resource Center's expertise available to all State Health entities.

5.6 Implementation Considerations

The SGA proposal framers describe the project as "a technical solution" that is based on basic business rationale which emphasizes the central role of communications with Resource Centers, uses existing network topography, leverages existing engineering expertise of carriers, and recognizes existing locations of concentrated HAN, Telemedicine, and Distance Learning services. Further, the approach is designed to: use 'best-practices' in network engineering to establish an industry standard (e.g., H.323); build a network around existing HAN, Telemedicine, and Distance Learning hubs; employ a Ring & Star configuration; and, provide ISDN gateways at primary hub sites. Indeed, Virginia is well positioned geographically and otherwise to advance the overall objectives of the SGA regional Telehealth network and to benefit from investments made to ensure the systems' implementation, operation and evaluation.

The SGA proposal further recommends 1.) Expanding the current HAN, Telemedicine, Distance Learning networks to enhance intra-state communications capabilities between the 15 states' Public Health Agencies and Emergency Management Command Centers, and 2.) Implementing infrastructure to provide inter-state communications between states with individual access to 3 National Resources and 36 Regional Resources. Based on preliminary reported technical data, the proposal also seeks to pilot test network implementation to establish interstate connectivity, access to resource centers, testing, benchmarking and operational readiness through networking resource centers, state public health agencies and emergency management command centers. The proposal reflects a rapid response to real demands for ensuring the physical and functional network infrastructure—Phase I Implementation has an estimated duration of four months.

Phase II, with an estimated duration of eight months, aims to expand network capacity through additional interstate connections, redundancy and network management capabilities. The goal is to connect 19 Switching Nodes, 15 State Public Health Agencies and Emergency Management Command Centers, and 12 Regional Resource Centers. Phase III, will expand the network capacity by connecting 12 additional Regional Resource Centers to include also operations and staffing for network monitoring services. The fourth phase provides for additional capacity and redundancy to support growth in network utilization, enhanced technological capabilities with additional security and network control. The total estimated project duration is 24 months.

The estimated benefits of operationalizing the proposed SGA TM/TH network include enhanced effectiveness, efficiencies and equities in TM/TH services. These are achieved through collaboration that leverages and expands existing infrastructure; supports the rapid and secure dissemination of information throughout the region on demand, and in the event of emergency situations; provides capacity for increased use of Telehealth services; and expands the region's ability to share health information and consultative expertise. The project includes:

- **An analysis**, via the survey, of the two-way video conferencing capabilities within the Health Alert Networks (HAN), telemedicine and distance health education infrastructures that currently exist and an identification of where additional infrastructure could be added in each state and regionally;
- **A vision of a regionally connected network** that uses the current HAN, telemedicine and distance health education systems, as identified through the survey, to prepare for and respond to health emergencies, and
- **A plan/blueprint** of what it will take to connect 88 sites throughout the South, including state public health agencies, state emergency management command centers, telemedicine centers, national resources like the CDC, Fort Detrick and NIH, and 36 other health-related resources from across the region.

5.6.1 Gaps and Critical Infrastructure

The research conducted in this study includes analysis of previous Virginia TM/TH reports, interviews with representatives of programs and agencies, reviews of the literature and policies at the national and state levels. Taken together, they provide strong and consistent evidence of gaps with respect to data, technology, policies, and regulations that warrant a comprehensive, systematic and strategic approach that involves representatives across multiple disciplines from both the public and private sector, local and state levels, as well as consumers, providers, and payers.

6 DEVELOPING A FRAMEWORK FOR EVALUATION OF TELEMEDICINE PROGRAMS AND SERVICES IN VIRGINIA

Based on the literature review, there are several key evaluation elements that should be explicitly articulated to frame any evaluation. Among the key evaluation elements relevant to telemedicine evaluation are: specification of the stage of project or program (design, implementation, monitoring, evaluation stage); enumeration of specific evaluation goals and objectives (clinical, cost, technical); selection of measurements and standards from among appropriate published and emerging guidelines; communication of the study perspective (health systems delivery, organizational, provider or other professional, or consumer). Key features for Virginia's consideration in the future are presented below.

6.1 Scope of the Evaluation

For Virginia, the purpose and accountability for on-going evaluations should be established. The scope of evaluation should be linked directly to the policy and programmatic goals. As has been noted by Sisk and Sanders, a "Fundamental question for evaluation is how services—whether preventive, diagnostic, therapeutic, or rehabilitative—delivered through telemedicine compare with those delivered through alternative means"[65]

6.2 Phases of the Telemedicine Evaluation Process

Develop an evaluation plan as an essential component of the telemedicine program design. Several important elements are defined in this step:

- Objectives,
- Methodology – study design, timelines, data needs and standards for data collection, quantifiers and data collection methods for non-tangible benefits, standards for analysis and communicating the results,

Establish a monitoring procedure throughout the program, to check if the evaluation component is functioning as planned;

Review of the evaluation results to verify if initial objectives have been met, and what are the main factors that determined the success or failure of the program; and

[65] Excerpt from Sisk, J.E., and Sanders, J.H. A proposed framework for economic evaluation of telemedicine. Telemedicine Journal 4(1): 31-7.

Re-design the program in accordance to the evaluation findings. This also includes a re-assessment of the evaluation process itself.

6.3 Evaluation Framework Elements

Several key framework elements, introduced below, are categorized along single dimensions. However, an evaluation framework typically is comprised of features across a number of these elements, as appropriate. Again, the goals and objectives of the evaluation should be the driver on the choice of elements included in the evaluation design.

- *Clinical*
  - Acceptance by consumers, carriers and health-care providers?
  - Access and equity - Does telehealth increase or redress access and equity for consumers and health professionals in rural and remote areas? What about consumers in urban areas as well who may be a significant distance from medical services, have poor transportation etc?
  - Change in work practices and reorientation of resources?
  - Consultation techniques?
  - Cultural and demographic differences?
  - Patient/client outcomes?
  - Quality (and continuity) of care - Are health care processes and outcomes generally improved by telehealth compared with the alternatives?
  - Quality of life?
- *Cost/benefit/effectiveness*
  - Is telehealth a good investment for the purpose compared to alternatives, in particular, current traditional methods of service delivery?
  - Is the system affordable, easy to use?
  - What are the costs and benefits of the system in day-to-day operations?
- *Technical acceptability - Is the system technically acceptable? For example, what is the:*
  - Difference between desktops and group-based systems?
  - Image quality?
  - Impact of difficult applications in difficult situations?
  - Video and sound quality?
- *Health systems interface - How well is the system integrated into the overall health system*?

- *Organizational issues*
  - Policy framework
  - Technical and administrative support
  - Training
- *Professional development*
  - Education and training outcomes
  - Group support and networking
  - Professional supervision
  - Recruitment and retention
- *Consumer perspective*
  - Impact on rural and remote communities
  - Privacy of medical records, consultation

7 RECOMMENDATIONS

7.1 Recommendations for Establishing a Mechanism to Support State-wide Strategic Planning for Telemedicine and Telehealth

In the face of shifts in national policy and public health goals, the planning process should include leadership representation from each state agency and leverage existing systems including the public health infrastructure to ensure efficient, effective access for public health surveillance as well as preventive and primary health care for the citizens of the Commonwealth of Virginia. Building on recommendations from previous Telemedicine reports (under Governors Allen and Gilmore) and based upon state and national trends, recommendations for Virginia are as follows:

- Implement a comprehensive and integrated statewide telemedicine/telehealth (TM/TH) infrastructure strategic planning process.
- Establish and communicate specific authorities and particular roles for state agencies, committees, commissions, and work groups with respect to the:
  - *physical infrastructure* (existing telecommunications and health care resources within the state) and
  - *functional infrastructure* (administrative, bureaucratic, programmatic and political).
- Establish collaborative systems to ensure interoperability and operations among entities with authority and responsibility to process data and information.
- Coordinate processes for data and information collection, management, reporting and dissemination using standardized frameworks and tools appropriate to the task for policy and program planning within each agency.
- Create a framework for evaluation of future telemedicine/telehealth activities in the Commonwealth using the mechanisms and elements drawn from prior evaluation frameworks described within the current study.

7.2 Recommendations Specific to the Evaluation Process in the Commonwealth of Virginia

Several recommendations specific to the telemedicine evaluation process have been developed:

- Develop an integrated evaluation methodology at the state level, which includes establishing of data standards and uniform collection methods, and feedback loops to assure a timely re-designing of the program, if needed.

- Include or promote inclusion of consistent evaluation processes as an essential component in designing any future telemedicine programs.
- Discuss adoption of similar data definitions, measurement, and collection methods at regional level (e.g. with SGA members).
- Develop a plan for future research activities, especially in emerging domains like using telemedicine for bio-preparedness education and training programs, as well as for emergency communications and crisis management, including diagnosis and treatment.
- Develop a plan for infrastructure development and investment in telemedicine and communication technology based on calculated future needs and availability of funds.
- Assess the need for future education and training programs—with an emphasis on public health-- for providers, institutions, and communities.

8 APPENDICES

8.1 Appendix A: Authority for the Study

The Virginia General Assembly approved Senate Bill 1214 of the 1999 Session and the Governor signed the bill amending the Code of Virginia as follows:

§32.1-19.1. Reporting of Telemedicine Initiatives.
The Commissioner shall annually report to the Governor and the General Assembly on the status of telemedicine initiatives by agencies of the Commonwealth. For the purposes of this section, telemedicine shall mean the use of telecommunications technology to deliver health care services and health professional education to sites that are distant from the host site or educator.

The report shall be issued by October 1 of each year and shall include, but not be limited to, (i) a summary of telemedicine initiatives by agencies of the Commonwealth; (ii) an analysis of the cost-effectiveness and medical efficacy of health services provided using telemedicine; (iii) recommendations regarding any improvements needed in current telemedicine initiatives; and (iv) identification of additional opportunities for use of telemedicine to improve access to quality health care and to health professional education for citizens of the Commonwealth.

8.2 Appendix B - Comparison of previous telemedicine reports in the Commonwealth of Virginia 1996-2001

Title, Year	State Entity	Authority for the Study	Definition of Telemedicine	Select Findings	Recommendations
Study of Telemedicine Pursuant to HJR 455 of 1995, House Document No. 6, 1996.	Joint Commission on Health Care, Commission on Information Management, and the Department of Information Technology	House Joint Resolution (HJR) 455 from the 1995 Session. To evaluate the use of telemedicine to provide better more accessible medicine to the citizens of the Commonwealth	Telemedicine is the use of telecommunications technology to deliver health care services and health professions education to distant sites. The spectrum of potential telemedicine applications ranges from medical consultation via telephone, to electronic transfer of radiology tests, to medical diagnosis and consultation via interactive television (IATV), where in a patient in a rural hospital can be seen by a specialist at a distant medical center over a live audio-video link. TM may be used to delivery both clinical and educational services including: • Medical consultation • Research and education • Medical management • Diagnostic consultation using medical records and test results 1. Improve the integration of public health and primary care (childhood vaccines) 2. Support research in clinical pathways (i.e., decision-making) 3. Support patient information systems for managed care networks • Distance learning Interactive Medical diagnosis and consultation	It is difficult to conduct comprehensive cost-benefit analysis of IATV telemedicine because of the high percentage of uninsured in rural areas. Most third party payers are reluctant to pay for 'high-end' IATV telemedicine, thus requiring grants or public subsidies. Some rural areas that desire IATV, lack the technical telecommunications access. The primary focus of studies has been on 'high-end technology, while there are many less sophisticated and less costly telemedicine applications that can improve health care and education.	The report recommended that the Commonwealth review and consider a variety of ways to support the continued growth and evaluation of telemedicine development including: • reimbursement by state health programs • DOC and AHEC to establish additional consultative services • Virginia Health Care Foundation to extend primary & preventive TM programs to the uninsured • CIM to evaluate roadblocks to implementation in rural VA
Reimbursement for Telemedicine Services, House Document No. 51, 1997	Secretary of Administration and Secretary of Health and Human Services.	HJR 109 directs the Secretary of Administration and the Secretary of Health and Human Services to develop a policy for considering the reimbursement for telemedicine services by state health programs, including, but not limited to, interactive television services, subject to appropriate standards of cost-effectiveness and quality assurance.	Telemedicine is broadly defined as the use of telecommunications technology to deliver health care services and health professions education from a central site to distant areas. However, for purposes of this study, telemedicine means the practice of health care delivery, diagnosis, consultation, treatment, transfer of medical data and education using Interactive audio, video and data communications (p. 12).	The Committee found no apparent consensus about the use of technology and those responsible for managing payment; in particular, the report identified three major topics impacting reimbursement: Absence of coordinated action by providers and state governments; Lack of acceptance by third-party payers; and, Lack of knowledge about telemedicine.	The report recommendations for establishing TM reimbursement polices across state programs included Legislation to: recognize TM without requiring person-to-person provider contact; conduct health services research addressing TM quality and efficiencies; require evaluation of all state-reimbursed TM services using standardized methodologies; promote TM use and research and monitor federal TM polices to ensure state-level consistency through the JCHC in conjunction with the CIM.

Title, Year	State Entity	Authority for the Study	Definition of Telemedicine	Select Findings	Recommendations
Barriers to the Implementation of Telemedicine in Virginia, House Document No. 31, 1997 (one of two reports responding to 1997 GA)	Secretary of Administration and Secretary of Education.	JR 53 of the 1995 Session of the General Assembly to evaluate roadblocks to the implementation of telemedicine applications in rural Virginia and recommend legislative or regulatory activity.	Telemedicine is broadly defined as the use of telecommunications technology to delivery health care services and health professions education from a central site to distant areas. For purposes of this study, telemedicine means the practice of health care delivery, diagnosis, consultation, treatment, transfer of medical data and education using 'store and forward' systems such as image transfer and interactive video, video and data communications.	Barriers to telemedicine were defined as societal practices and reactions rather than inherent limitations of the technology. Among the conclusions reached was that the value of TM systems to individuals and communities… exceeds dollars saved and the coordination of care… [Hence] the coordination of telemedicine services with other community needs and resources dramatically increases the value of such a system (p. 19).	Recommendations emphasized the need for collaboration among Virginia's academic institutions, public and private payers and other organizations including State Boards to address adequately a broad set of issues impacting the acceptance, cost, implementation, and utilization of TM in the Commonwealth. Recommendation number seven specifically called for the medical communities, providers of technology and communications companies…to fund and share the responsibility for establishing the needed telemedicine sites and for identifying the most appropriate and cost-effective telemedicine applications. Cooperation among these groups was also recommended in order to ensure comprehensive efforts aimed at: assessing cost-effectiveness; analyzing the impact of TM on provider practice patterns, local hospitals and communities.
Study of Reimbursement and Quality of Care Issues Regarding Telemedicine Pursuant to HJR 210, House Document No. 48, 1999.	Joint Commission on Health Care with the Department of Medical Assistance Services	HJR 210 1998 Session of the General Assembly to study reimbursement and quality of care issues; the experience of other states regarding reimbursement and development of reimbursement policies; identifying cost-effective services; appropriate role of the VDH in identifying medically underserved areas.	References the 1996 definition of telemedicine as the use of telecommunications technology to deliver health care services and health professions education to distant sites. Further, the report identifies specific applications as including but not limited to: The use of imagining technology to send or link: • Radiology images from a remote site; • Academic health center and a state correctional facility infirmary • A psychiatrist and a patient • Provider and home bound patient	In the face of newly named Secretary of Technology, the state would benefit from establishing formal roles in coordinating telemedicine activities with leadership assumed by the Commissioner of Health to ensure access to care among medically underserved areas and to report annually to the Governor. The study found that third party payers were obstacle to its growth and that coordination of licensure issues is appropriate.	Recommended that the Commissioner of Health play a greater role in monitoring the state's commitment and progress in telemedicine including: • Assessing three local VDH-sponsored programs • Demonstrating the cost-effectiveness and care quality • Monitoring impact on access to underserved areas Need to coordinate telemedicine among state agencies including ensuring compatible equipment.

Title, Year	State Entity	Authority for the Study	Definition of Telemedicine	Select Findings	Recommendations
Telemedicine Report, October, 1999.	Virginia Department of Medical Assistance Services	Pursuant to the 1999 Virginia Acts of Assembly Chapter 935 Item 335 DMAS shall (i) evaluate the initial results of its current telemedicine reimbursement policy; (ii) develop protocols to address documentation of services and confidentiality of patient information with regard to telemedicine; and (iii) identify any additional services for which telemedicine reimbursement would be medically appropriate and cost effective.	DMAS addressed[66] protocols including: • documentation of services and confidentiality of information • signed statement by the patient agreeing to the telemedicine encounter and • Signature of medical practitioner's office that staff has been trained in the telemedicine equipment.	DMAS concluded that telemedicine has significant potential to improve access to services but changes in reimbursement should be approached cautiously pending further evaluation.	DMAS should reimbursement for: • **Lengthier consultation** than those currently recognized by DMAS. Currently DMAS consultations via telemedicine can be upwards of 40 minutes. The lengthier consultation will allow for the treatment of more complicated medical conditions. These involve a more comprehensive examination and decision-making process • **Non-physician, DMAS-enrolled providers** participating in telemedicine consultations with DMAS-enrolled medical specialists. • **Provision of "store and forward" telemedicine**... limiting reimbursement for store and forward to physicians enrolled with DMAS.
Telemedicine Study, October 1999. Senate Document 18, 2000.	Virginia Department of Health	Pursuant to Senate Bill 1214 (1999) and Budget Item 333 j, the Commissioner shall annually report to the Governor on the status of telemedicine initiatives by agencies of the Commonwealth.	Specifically, telemedicine in this report refers to communication for clinical consultation or education between "host' and 'remote' sites using technologies other than telephone and fax (p.6).	This report included a summary of the telemedicine sites associated with state agencies and presented the study design developed under contract with the Division of Quality of Health Care, Department of Internal Medicine of VCU to design the prospective study instrument for subsequent use comparing all telemedicine initiatives in the Commonwealth.	Recommended the development of a comprehensive data collection and evaluation instrument to include: Facility descriptions Finances and development plan including marketing and business Personnel Program scope and demographics of prospective and actual patients Utilization and clinical characteristics Additional cost-effectiveness variables Hardware and technologies employed Clinical and other outcomes as available.

[66] DMAS telemedicine report 1999, page 6.

Title, Year	State Entity	Authority for the Study	Definition of Telemedicine	Select Findings	Recommendations
Telemedicine Study January, 2001. Senate Document 28, 2001.	Virginia Department of Heath.	Pursuant to Senate Bill 1214 (1999) and Budget Item 333 j, the Commissioner shall annually report to the Governor on the status of telemedicine initiatives by agencies of the Commonwealth.	Telemedicine shall mean the use of telecommunications technology to delivery health care services and health professions education to sites that are distant from the host site or educator.	This second annual report from the VDH, presents the results of the completion and field testing of the study data collection instrument. Twenty-one (21) representatives of selected Virginia telemedicine programs were interviewed and preliminary evaluation assessment instruments were developed, which aim to support cost-effectiveness evaluation. Of telemedicine programs.	Four recommendations were made to the State Health Commissioner: 1. Use the recommended evaluation instruments to establish a baseline assessment of the telemedicine programs and initiate a continuous quality improvement and evaluation process. 2.) Continue the TM Program Working Group at the VDH to direct the continuing TM evaluation including collaboration and development of TM initiatives by agencies of the Commonwealth; 3.) For the VDH TM sites, ensure integration of technology through the use of an integrator. 4.) Involve local communities, especially local physicians, in the development of TM programs.
A Joint Study to Establish Guidelines for Ensuring Compatibility Among Telemedicine Equipment, House Document No. 18, 2000	Report conducted by the Department of Technology Planning and the Secretary of Health and Human Services and submitted to the Joint Commission on Health Care.	HJR 683 directed by the Secretary of Technology to develop guidelines for ensuring compatibility among telemedicine equipment operated by state agencies including but not limited to: Department of Corrections; VCU-MCV, EVMS, UVAHSC, MC Hampton Roads, DMHMRSAS, and VDH.	Rather than traditional face-to-face structure, health care professional to patient, telemedicine (TM) allows the separation of the two by a physical distance, with services via electronic linkage. Thus, telemedicine or, more broadly, telehealth (TH) offers one of the most significant and dramatic changes in the practice of health care that has been seen in the United States since its founding in 1776…TM/TH is an area where public and private benefits converge [to improve …how health care is provided in the future (GAO: 1997).	Framers of the study concluded in advance that the study would be more beneficial if the scope extended beyond 'guidelines for ensuring compatibility among telemedicine equipment" and accordingly other TM/TH issues based on previous studies were updated in the report. The report concluded, based on a review of technology (telecommunications, hardware and software) usages in support of telemedicine and telehealth TM/TH, that existing technology standards were sufficient to support telemedicine initiatives. It further concluded that Lack of a comprehensive state-wide planning is an impediment to TM/TH projects. Barriers at the national and state level s require collaboration across public, private and reimbursement sectors.	Seven recommendations were put forward including: 1.) establishing a broad state-level comprehensive approach to ensure the economic development of TM/TH: 2.) establishing a technology planning work group under Secretary of Technology Council on Technology Services (COTS); 3.) Maintain an enhanced TM/TH Web-site; 4.) Create a formal Telecommunication Technical Task Force comprising representatives form medical, academic, state and local agencies, and TM/TH vendors to review standards; 5.) TM/TH Work Group should advise the Department of Information Technology on equipment and services; 6.) Establish a liaison for state input from Federal TM/TH initiatives; 7.) Authorize additional JCHC studies (e.g., standardized data systems, CB-CE analysis and barriers).

8.3 Appendix C: Studies of Patient/Physician Satisfaction

HHS 2001 Report to Congress on Telemedicine: Studies of Patient/Physician Satisfaction

Name of Report	No. of Studies Reviewed	Patient Satisfaction	Provider Satisfaction	Strengths/ Weaknesses
DHHS/Oregon Health Sciences University (2000)	30 studies	Highly Satisfied	Highly Satisfied	Large survey of studies/ small data samples in each study. Studies only look at one application such as teledermatology
East Carolina University (2000)	12 studies plus ECU study of 492 teleconsults	Highly Satisfied 98.3% Rating	NA	Large data sample in ECU study with different applications and different settings/ small survey of 12 other studies with small data samples.
Association of Telehealth Service Providers (1999)	Study based on 132 network responses	NA	Moderate to Highly Satisfied	Large survey of users/ only looks at technology and users

8.4 Appendix D: States Where Medicaid Reimbursement of Services Utilizing Telemedicine is Available

Source: HHS, Centers for Medicare and Medicaid

STATE	Payment Method FFS+ Same Coverage as Traditional Face-to-Face at Both Hub and Spoke Unless Indicated*	*PROGRAM DETAILS*
Arkansas	FFS	The Medicaid Agency recognizes physician consultations when provided using interactive video teleconferencing
California	FFS	Recognizes physician consultations (medical & mental health) when furnished using interactive video teleconferencing.
Georgia	FFS	Recognizes physician consultations when furnished using interactive video teleconferencing.
Illinois	FFS	Recognizes physician consultations when furnished using interactive video teleconferencing.
Iowa	FFS	Recognizes physician consultations when furnished using interactive video teleconferencing.
Kansas	FFS – HUB ONLY	Recognizes home health care and mental health services already covered by the state plan when furnished using video equipment. Home health is limited to certain services. Compensation for home health care via telemedicine is made at a reduced rate. Reimbursement is made for only the service furnished at the hub site.
Louisiana	FFS	The Medicaid agency recognizes physician consultations when furnished using interactive video teleconferencing. Physician Assistants are allowed to perform the service using telemedicine if they are authorized by a primary physician, who also has to bill the program for services provided.
Minnesota	FFS	Recognizes physician consultations (medical and mental health) when furnished using interactive video or store-and-forward technology. Interactive video consultations may be billed when there is no physician present in the emergency room, if the nursing staff requests a consultation from a physician in a hub site. Coverage is limited to three consultations per beneficiary per calendar week. No payment is made for transmission fees.
Montana	FFS	Recognizes any medical or psychiatric service already covered by the state plan when furnished using interactive video teleconferencing.
Nebraska	FFS	Recognizes most State plan services when furnished using interactive video teleconferencing. In general, services are covered so long as a comparable service is not available to a client within a 30-mile radius of his or her home. Services specifically excluded include medical equipment and supplies; orthotics and prosthetics; personal care aide services; pharmacy services; medical transportation services; and mental health and substance abuse services and home and community-based waiver services provided

		by persons who do not meet practitioner standards for coverage. Payment for transmission costs is set at the lower of the billed charge or the state's maximum allowable amount.
North Carolina	75/25 Rule Consulting Hub/Spoke	Recognizes initial, follow-up or confirming consultations in hospitals and outpatient facilities when furnished using real-time interactive video teleconferencing. The patient must be present during the teleconsultation. Payment is on a fee-for-service basis.
North Dakota	FFS	The Medicaid Agency recognizes specialty physician consultations when furnished using interactive video teleconferencing.
Oklahoma	FFS	Recognizes physician consultations when furnished using interactive video teleconferencing.
South Dakota	FFS	Recognizes physician consultations when furnished using (interactive & non-interactive) video equipment.
Texas	FFS	Recognizes physician consultations (teleconsultations) when furnished using interactive video teleconferencing. Reimbursement is made at both ends. Other health care providers, such as advanced nurse practitioners and certified nurse midwives are allowed to bill, as are Rural Health Clinics and Federally Qualified Health Centers.
Utah	FFS (MH: HUB ONLY)	The Medicaid agency recognizes the following services when furnished using interactive video teleconferencing: mental health consultations provided by psychiatrists, psychologists, social workers, psychiatric registered nurses and certified marriage or family therapists; diabetes self management training provided by qualified registered nurses or dieticians and; services provided to children with special health care needs by physician specialists, dieticians and pediatricians when those children reside in rural areas. Reimbursement is made at both the hub and spoke sites for diabetes self-management training services and services provided to children with special health care needs. Reimbursement is made only to the consulting professional for mental health services. Payment is made for transmission fees.
Virginia	FFS	Recognizes, as a pilot project, medical and mental health services already covered by the state plan when furnished using interactive video teleconferencing.
West Virginia	FFS	The Medicaid Agency recognizes physician consultations when furnished using interactive video teleconferencing.

8.5 Appendix E: National Conference of State Legislature's Telemedicine Legislation

8.6 Appendix F: Telemedicine Licensure - State legislation

STATE	STATUTE	PHYSICIANS	NURSES
Alabama	Code §§ 34-24-502,503,507 (1997	Special licensure for out-of-state physicians	
Arkansas	Code Ann. § 17-95-206 (1997). Arkansas Session Law 220 (1999)	Full licensure for out-of-state physicians (1997)	Nurse Licensure Compact (1999)
California	Business and Professional Code §§ 2060,2290.5,2052.5 (1997	Registration program for telemedicine providers created by Board of Medicine	
Colorado	Rev. Statute Ann § 12-36-106 (1998). SB 19 62nd Legislature	Full licensure for out-of state physicians Limited license for physicians affiliated with Shriners Hospital for Children (1999)	
Connecticut	General Statute § 20-9 (1997).	Full licensure for out-of-state physicians	
Delaware	HB 439 (1999)		Interstate Nurse Licensure Compact (2000)
Georgia	Code Ann. § 43- 34- 31.1 (1998).	Full licensure for out-of-state physicians	
Hawaii	§ 453-2 (1997). SB 1136 (1999)	Permits out-of-state physicians without in-state offices to practice telemedicine State licensure not required if out-of-state physician is providing consultation to an in-state licensed physician (1999)	
Illinois	Comp. Statute 60-49.5 (West 1998).	Full licensure for telemedicine practitioner	
Indiana	Code Ann. § 25-22.5-1-1.1 (Michie1998).	Full licensure to practice telemedicine	
Iowa	HF 2105 (3/2000		Interstate Nurse Licensure Compact
Kansas	Administrative Regulations § 100-26-1 (1996).		
Maine	ME LD 2558 (2000).		Interstate Nurse Licensure Compact
Maryland	SB 490 (1999)		Interstate Nurse Licensure Compact
Mississippi	Code Ann. § 73-25-34 (1997). MS HB 535 (2000)	Full licensure for out-of state physicians practicing telemedicine	Interstate Nurse Licensure Compact
Montana	HB 399, 56th Legislature (1999)	Telemedicine certificate issued by Board of Medical Examiners	
Nebraska	Rev. Statute § 71-1,102 (1998). NE L.B.	Full licensure for out-of-state physicians	Interstate Nurse Licensure

	523 (1999).		Compact effective 7/1/2000
Nevada	Rev. Stat. Ann. § 630-020- (Michie 1997). Nev. Rev. Stat. Ann. tit. 54 ' 630.020 (2000)	Full licensure for out-of-state physicians practicing telemedicine. Exemption for physicians called into the state by a licensed in-state physician for a consultation on an irregular basis	
New Hampshire	SB 53 (1999)	Full licensure for out-of-state physicians providing contractual or frequent teleradiology service to NH patients	
North Carolina	General Statute § 90-18 (1997). N.C. Sess. Law 1999-0245 '90-171.80 - 171.93 (1999)	Full licensure for out-of-state physicians	Interstate Nurse Licensure Compact (effective 7/1/2000)
North Dakota	HB 1158 (1999)	Full licensure required unless out-of-state physician is in consultation with in-state licensed physician physically located in ND and primarily responsible for the care of patient	
Oklahoma	Statute title 36, § 6802(1997)	Full licensure for out-of-state physicians	
Oregon	SB 600 (1999)	Special purpose telemedicine license for out-of-state physicians. Allows consultations and emergency care without license.	
South Dakota	Codified Laws § 36-4-41- (Michie 1998) SD H.B. 1045 (2000).	Full licensure for out-of-state physicians, using electronic means to treat persons located in SD.	Interstate Nurse Licensure Compact, effective 1/1/2001.
Tennessee	Code Ann. § 63-6-201 (1998), Tenn. Comp. R.& Regulations Chap 0880-21.16 (1998)	Special purpose license for out-of-state physicians	
Texas	Rev. Civ. Stat. Art. 4495b, §3.06 (I) (1998), 22 Tex. Admin. Code §§ 174.1-174.15 / HB 1342, 76th Legislature (1999)	Special purpose license for telemedicine practitioners (1998)	Interstate Nurse Licensure Compact, enacted 6/19/99
Utah	Code Ann. § 58-31b-102 (1998), Utah Code Ann § 58-1-307 (1998), SB 26 (1999)	Full licensure for out-of-state physicians	Interstate Nurse licensure compact, effective 1/1/2000
West Virginia	HB 2082, 74th Legislature, (1999)	State licensure for the practice of telemedicine with some consultation exceptions.	
Washington	WI A.B. 305 (1999).		Interstate Nurses Licensure Compact effective 1/1/2000
Wyoming	Rules 024-052-001 § 4(d) (1998)	Full licensure for out-of-state physicians	

8.7 Appendix G: Malpractice Liability Summary Chart

MALPRACTICE LIABILITY ANALYSIS

1. PROVIDER LIABILITY

- Duty of care: *Has a patient-physician relationship been established? Do the secondary and tertiary consultants also have a duty toward the patient?*
- Breach of the standard of care: *Which is the standard of care that applies to this case (i.e. locality rule, statewide, or national standard)? Was there a breach of this standard of care?*
- Causality: *Was there a causal relationship between the provider's breach of standard of care and patient's harm?*
- Harm: *Assessing the harm and damages resulting from the provider's negligence.*

2. INSTITUTIONAL LIABILITY

- Vicarious liability: *Was the negligent provider an employee of the institution or perceived as such by the patient*?
- Direct liability: *Was the institution itself negligent by failing to maintain its facilities/equipment, monitor providers, and design programs to increase the quality of care?*

8.8 Appendix H: The Joint Working Group on Telemedicine

According to its Mission Statement, the Joint Working Group on Telehealth (JWGT) is a Federal interagency group that coordinates members' telehealth activities. Several member agencies provide telehealth grants and the JWGT ensures that there is no overlap in Federal funding.

Members bring their unique telehealth expertise to the table, providing a forum to discuss and share information, to educate its members and to develop specific actions that reduce barriers to the effective use of telehealth technologies.

Federal agencies represented in the JWGT include:

- Appalachian Regional Commission
- Department of Agriculture
- Department of Commerce
- Department of Defense
- Department of Education
- Federal Communications Commission
- Department of Health and Human Services
- Department of Justice
- Department of State
- National Aeronautics and Space Administration
- Department of Veterans Affairs

8.9 Appendix I: Evaluating Quality of Care and Health Outcomes

SOURCE: EXCERPTED FROM THE IOM REPORT

What were the effects of the telemedicine application on the clinical process of care compared to the alternative(s)?

Was the application associated with differences in the:

- Use of health services (e.g., office visits, emergency transfers, diagnostic tests, length of hospital stay)?
- Appropriateness of services (e.g., underuse of clearly beneficial care)?
- Quality, amount, or type of information available to clinicians or patients?
- Patients' knowledge of their health status, their understanding of the care options, or their compliance with care regimens?
- Diagnostic accuracy or timeliness, patient management decisions, or technical performance?
- Interpersonal aspects of care?

What were the effects of the telemedicine application on immediate, intermediate, or long-term health outcomes compared to the alternative(s)?

Was the application associated with differences in?

- Physical signs or symptoms?
- Morbidity or mortality?
- Physical, mental, or social and role functioning?
- Health-related behaviors (e.g., compliance with treatment regimens)?
- Patients' satisfaction with their care or patients' perceptions about the quality or acceptability of the care they received?

Evaluating Access to Care

Did telemedicine affect the use of services or the level or appropriateness of care compared to the alternative(s)?

What was the utilization of telemedicine services before, during, and after the study period for target population and clinical problem(s)?

When offered the option of telemedicine service, how often did patients:

- Accept or refuse an initial service or fail to keep an appointment?

- Accept or refuse a subsequent service or fail to keep an appointment?

What was the utilization of specified alternative services before, during, and after the study period for the target population and clinical problem(s)?

- Consultants traveling to distant sites
- Patients traveling to distant consultants
- Consultation by mail or courier
- Transfers to other facilities
- Self-care

Was the telemedicine application associated with a difference in overall utilization (e.g., number of services or rate) or indicators of appropriateness of care for?

- Specialty care
- Primary care
- Transport services
- Services associated with lack of timely care?

Did the application affect the timeliness of care or the burden of obtaining care compared to the alternative(s)?

Was there a difference in the

- Timing of care
- Appointment waiting times for referrals?

What were patient attitudes about the

- Timeliness of care
- Burden of obtaining care
- Appropriateness of care?

What were the attitudes of attending and consulting physicians and other personnel about the

- Timeliness of care
- Burden of providing care
- Appropriateness of care?

Evaluating Health Care Costs and Cost-Effectiveness

What were the costs of the telemedicine application for participating health care providers or health plans compared to the alternative(s)?

Was an application associated with differences in the:

- Attending clinicians' costs for personnel, equipment, supplies, administrative services, travel, or other items?
- Revenues or productivity? What was the net effect?
- Consulting clinicians' or consulting organizations' costs for personnel, equipment, supplies, space, administrative services, travel, or other items?
- Revenues or productivity? What was the net effect?
- Cost per service, per episode of illness, or per member (health plan enrollee, capitated lives) per month?

What were the costs of the telemedicine application for patients and families compared to the alternative(s)?

Was the application associated with differences in direct medical costs for patients or families?

Was the application associated with differences for patients or families in other direct costs (e.g., travel, child care) or indirect cost (e.g., lost work days)?

What were the costs for society overall compared to the alternative(s)?

Was an application associated with differences in total health care costs, the cost per service, per episode of illness, or per capita?

How did the costs of the application relate to the benefits of the telemedicine application compared to the alternative(s)?

Evaluating Patient Perceptions

How did patients rate their physical and psychological comfort with the application?

How did patients rate the convenience of the encounter, its duration, its timeliness, and its cost?

How did patients (and family members) rate the skills and personal manner of the consultant and the attending personnel (e.g., primary care physician, nurse practitioner)?

Was the lack of direct physical contact with the distant clinician acceptable?

How did patients rate the explanations provided to them of what their problem was and what was being recommended?

Did patients have concerns about whether the privacy of personal medical information was protected?

Would patients be willing to use the telemedicine service again?

Overall, how satisfied were patients with the telemedicine services they received?

Evaluating Clinician Perceptions

Were attending/consulting clinicians satisfied with the telemedicine application compared to the alternative(s)?

How did attending/consulting clinicians rate the:

- comfort with telemedicine equipment and procedures?
- convenience of telemedicine in terms of scheduling, physical arrangements, and location?
- timeliness of consultation results?
- technical quality of the service?
- quality of communications with patients?
- Were attending/consulting clinicians concerned about maintaining the confidentiality of personal medical information and protecting patients' privacy?
- Did attending/consulting clinicians believe the application made a positive contribution to patient care?
- Would the clinicians be willing to use the telemedicine services again?
- Overall, how satisfied were the attending/consulting clinicians with the telemedicine service?

8.10 Appendix J: Department of Health and Human Services Strategic Plan FY 2003 - 2008 Draft - July 29, 2002

http://aspe.hhs.gov/hhsplan/draft/#execsum accessed September 4, 2002

Executive Summary

We have established eight (8) strategic goals for accomplishing the Department of Health and Human Services (HHS) mission to protect and improve the health and well-being of the American public. These goals and accompanying objectives provide the focus for HHS investments of effort and resources over the next five years. The following summary highlights the key priorities of the Secretary that are found in the plan:

To PREVENT DISEASE AND ILLNESS, Goal 1 is to "reduce the major threats to the health and well-being of Americans." To achieve our goal, we will focus on the behavioral and environmental threats that have a significant effect on health. We especially will focus on:

- Promoting healthy behaviors, such as regular exercise and a healthy diet to reduce obesity and the incidence of chronic diseases, such as diabetes;
- increasing abstinence education for young Americans and providing educational and other materials aimed at reducing unsafe sexual behaviors and preventing unintended pregnancies; and
- reducing substance abuse by expanding and improving communities' substance abuse prevention and treatment programs.

To PROTECT OUR HOMELAND, Goal 2 is to "enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges." To achieve this goal we will focus our efforts on:

- building the capacity of the health care system to prepare for and respond to public health threats, especially bioterrorism; and
- Initiating steps to ensure the safety of food, drugs, biological products, and medical devices.

To CLOSE THE GAPS IN HEALTH CARE, Goal 3 is to "increase the percentage of the Nation's children and adults who have access to regular health care and expand consumer choices." To achieve our goal, we plan to undertake a multi-faceted approach that includes:

- creating new, affordable health insurance options;
- expanding the health care safety net, especially in underserved rural and urban areas and for low income persons; and
- expanding the availability of health services for populations with special needs, such as those needing organ and tissue transplantations, persons with HIV/AIDS, and persons with mental illnesses.

To IMPROVE HEALTH SCIENCE, Goal 4 is to "enhance the capacity and productivity of the Nation's health science research enterprise." To achieve this goal we will concentrate on:

- making investments that advance the understanding of basic biomedical and behavioral science and how to prevent, diagnose, and treat disease and disability; and
- accelerating the development of new drugs, medical technology, and biologic therapies.

To REALIZE THE POSSIBILITIES OF 21st CENTURY HEALTH CARE, Goal 5 is to "improve the quality of health care services." For this goal, we will especially focus on:

- steps to reduce medical errors and improve consumer and patient protections; and
- accelerating the development and use of an electronic health information infrastructure.

To WORK TOWARD INDEPENDENCE, Goal 6 is to "improve the economic and social well-being of individuals, families, and communities, especially those most in need." Our efforts will concentrate on:

- engaging all welfare families in work leading to self sufficiency;
- reducing barriers to independent living for persons with disabilities; and
- expanding community and faith-based partnerships to find more creative and effective ways of delivering human services.

To LEAVE NO CHILD BEHIND, Goal 7 is to "improve the stability and healthy development of our Nation's children and youth." In achieving this goal we will focus on:

- promoting family formation and healthy marriages; and
- instituting creative and innovate ways to improve the learning readiness of preschool children.

To IMPROVE DEPARTMENT MANAGEMENT, Goal 8 is to "achieve excellence in management practices." To help us achieve the above seven program objectives, we will institute a multi-pronged approach to improve management practices and achieve excellence by focusing on the key areas in the President's Management Agenda. For example, management reforms will center on:

- Creating a unified "One HHS"
- Improving workforce planning and financial management;
- enhancing the efficiency and effectiveness of competitive sourcing; and
- Enhancing the use of electronic commerce.

8.11 Appendix K: Background Briefing. Health Insurance Portability and Accountability Act (HIPAA) and Privacy Rule Compliance Model

When the Health Insurance Portability and Accountability Act (HIPAA) was enacted, Congress recognized the need for national medical information privacy standards, justified by the significant technological advances and the serious gaps in the patient privacy protection left by existing federal and state law. Before HIPAA, the privacy of medical data had been regulated by non-uniform state laws that vary from strict (e.g. Rhode Island and Wisconsin) to permissive legislation, mostly with condition-specific requirements (i.e. usually stigmatized illnesses). The new federal legislation will preempt only the weaker state laws, but not those that provide stronger patient provisions, still applicable.

HIPAA consists of seven principal standards united in the Administrative Simplification regulations. Only the privacy standard will be addressed in this section. Standards for national identifiers, electronic transaction codes and data security will be discussed later in the report, along with other federal/legal mandates. HIPAA as a whole serves two major purposes:

- To reduce the administrative burden of healthcare entities (e.g. filling claims, billing, checking eligibility for treatment, paying premiums, all streamlined by implementing medical records systems).
- To protect individually identifiable health information.

The *Privacy* Standard was published by HHS as a proposed rule in November 1999, after the Congress failed to adopt privacy legislation, and as a final rule in December 2000. After the comment period, the Bush administration allowed it to take effect on April 14, 2001, with the mention that it may recommend changes to the rule before its implementation deadline. Changes were proposed in May 2002, and the final version of the regulation was published on August 14, 2002.

2.3.1 Schedule for Compliance with the HIPAA Final Rule's Provisions

The majority of health plans, providers and other covered organizations have two years to comply with the *Privacy* provisions. The general deadline was set for April 14, 2003. Small health plans received an additional year, until April 14, 2004. Health institutions can also apply for a one-year extension of the required changes in business associates contracts, and have time until 2004 to amend contracts as they are up for renewal. Final modifications include models of business associate contracts that covered entities may use to ensure their partners' HIPAA compliance.

2.3.2 Entities Covered by HIPAA

The Privacy rule applies to three types of entities (as HHS defines them):

- Health plans (all types)
- Healthcare clearinghouses (e.g. billing companies)

- Healthcare providers who transmit (or hire someone to) individual health information in electronic form.

Broadly defined, all categories of healthcare providers are included (individuals or institutions) that provide, directly or indirectly, or are paid for health services. Through the covered entities described above, the rule also applies to their business associates that receive patient information to provide services (legal, financial, accounting, claim processing, etc). The primary three categories of organizations targeted are responsible for developing contracts that require their business partners to comply with the *Privacy* rule. Thus, telemedicine programs, systems, and services must comply with the rule, as well as with the rest of the HIPAA legislation.

2.3.3 Type of Information Protected

Even though many believe that the original HIPAA language was ambiguous, HHS final rules specified that all types of "individually identifiable health information used or disclosed by a covered entity in any form, whether electronically, on paper, or orally, are covered by the final rule."

2.3.4 Consumer Control

In the original rule, regulations gave patients the right to receive explanations about how their data will be used, access their medical records and make amendments if necessary, and obtain a count of "non-routine" disclosures of their information. The HHS rule stipulated that health providers would be required "to obtain patient consent before sharing their information for treatment, payment, and healthcare operations." However, providers or health plans could condition the provision of care or enrolment, respectively, on the patient's signature of the consent form. For all other non-health uses of PHI, a separate patient authorization was needed. The refuse to sign this second authorization form could not constitute a condition for providing care or enrollment in a health plan.

Under the modified final *Privacy* rule, published in August 2002, the requirement for the patient consent before any PHI disclosure was replaced with a requirement for providers to "notify patients about their privacy rights and [providers'] practices." Covered entities must make "reasonable" efforts to secure a patient acknowledgement of receipt of the privacy rights and practices notice. The use of consent forms for PHI disclosure becomes optional. Changes refer only to health-related disclosures. For all other purposes, specific patient authorization is still needed. HHS argues that these changes to the initial rule were intended to protect privacy while eliminating barriers to treatment.

Patients will also be able to obtain a copy of their medical records, and to request correction of any errors. They can also obtain an accounting of non-medical disclosure of their information from each entity involved.

2.3.5 Principles of Medical Record Use and Release

The principle emphasized in the initial privacy rule was that covered entities should make efforts to disclose only the "minimum amount of information necessary for the purpose of disclosure." This provision, however, raised serious concern about how the "minimum necessary' is defined, and what are

the implications for providers. The second principle is that PHI should be used, to the extent possible, only for health-related purposes. For all other uses specific authorization from the patient is needed.

The "minimum necessary" requirement for disclosure was amended in the final modified rule to allow customary practices -- like reading patients' names aloud in a waiting room, or a low-voice conversation in a semi-private hospital room-- to continue if reasonable safeguards are in place.
Covered entities must have individual's authorization before disclosing his information for marketing purposes.

Disclosure of PHI for marketing purposes can be done only with patient's authorization, wit the exception of a "face-to-face encounter or a communication involving a promotional gift of nominal value." For example, doctors and health plans can talk to their patients abut treatment options or other services offered without a specific authorization for marketing. Pharmacies, however, cannot send patients marketing materials or sell their health information without prior consent. Business associate agreements cannot be used to circumvent these consent requirements.

Other changes refer to the initial rule consist of consolidating authorization forms for non-routine use or disclosure; disclosure for research purposes, which can use one form to obtain authorization for research and for disclosure of patient's medical information. Limited data sets that do not include the patient's identifiable information, can be created and disseminated to be use for research public health, and health care operations, without individual consent.

2.3.6 Permitted Disclosures without Consent

Certain disclosures are permitted without the individual's consent. These include public responsibilities like law enforcement and national security, public health activities, emergency situations, institutional oversight, and research activities in specific circumstances:

- Abuse, neglect, or domestic violence
- Decedents or donated tissues and organs
- Disclosures required by federal and state law
- Governmental functions like military, national security
- Governmental oversight activities, including licensing and fraud and abuse investigations
- Judicial and administrative proceedings
- Law enforcement
- Public health purposes – vital statistics, communicable diseases, adverse event reporting for FD-regulated products, and so on
- Research – like epidemiological studies or record reviews
- Threats to public health or safety
- Workers' compensation disclosures

2.3.7 Estimated Cost of Implementation

While HHS estimated the cost of the *Privacy* rule implementation at $17.6 billion over 10 years, the majority of covered entities argue that the implementation will be far more expensive. It is difficult to estimate the cost of implementing the rule in Virginia at this point. Also, there is no data available to suggest the costs pertaining exclusively to telemedicine out of the total. However, since telemedicine programs and services are more likely to have patient data stored, and to necessitate transmission of data at a distance, the costs of implementing the Privacy rule will probably be higher than for traditional services, due to additional needs for security.

2.3.8 Relationship with Existing State Confidentiality Laws

The HIPAA *Privacy* requirements are intended to become a national standard in protecting PHI. However, where state laws are stronger, they would prevail. Laws that are weaker than HIPAA are preempted, except those that refer to regulating insurance, substance control, or health reporting requirements. The final modifications to the *Privacy* rule also emphasize that HHS did not intend to limit parents' access to their minor children information, and recognize the supremacy of state laws in this field. When there are no specific state laws, each provider would have the discretion to decide the parents' access to their children private health information. In the light of this HIPAA provision, VDH and the Commonwealth of Virginia should analyze state legislation and regulations regarding parents' consent and access to information, and decide on a state-level policy to be followed by all health providers.

2.3.9 Privacy Safeguard Standards

To ensure that the standards are followed, covered entities have to implement privacy compliance programs. Each program must have a Privacy Officer to oversee it, adopt written privacy policies and procedures, and have an employee training program, and a patient complaint system in place.

2.3.10 Accountability and Penalties

HIPAA/Privacy rule establishes civil penalties of $100 for each violation, up to a total of $25,000 per person/year, for each requirement violated. For those who are knowingly violating HIPAA provisions, there are also criminal penalties of up to $250,000 and up to 10 years in prison for most serious violations.

2.3.11 Compliance and Enforcement

The *Privacy* rule will be enforced by the Office for Civil Rights within HHS. People have the right to fill a complaint with the covered entities, as well as with HHS, for any claim of privacy violation. Individuals cannot directly sue any covered entity for privacy violations under HIPAA.

2.3.12 Conclusions

By its nature, telemedicine is more exposed to security and privacy breaches than the traditional health care. The provision of telemedicine services includes extensive transmission of patient data among

different providers, and over the Internet. Adequate security systems should be in place even before the HIPAA/Privacy rule implementation deadline, and the patients must be informed of the transmission procedures, persons who will be seeing the information, and where are the data going to be stored after the consult. Under the modified rule, the patient consent for disclosure of PHI is optional, being replaced by an acknowledgement of a notice of policies and procedures.

Telemedicine Services are considered "covered entities" under the *Privacy* rule and, therefore, have to satisfy all requirements. Particular attention should be given, however, to interstate consults, where two or more state laws, potentially not preempted by HIPAA, have to be taken into account.

In a recent article on health information privacy protections, Kumekawa[67] suggests that HIPAA can affect telemedicine providers especially through its federal preemption of state law that conflict or are weaker than the federal requirements. States with stronger patient privacy protections in place would continue to apply their laws instead of the federal legislation. The result will be a mixture of legal requirements and standards that would further complicate the practice of telemedicine across state lines. More requirements mean increased expenses, thus the costs of telemedicine activities are expected to be higher for interstate consults, in part because of the variations in privacy legislation.

With funds from the DHHS, Kumekawa explains, the Advanced Technology Institute's (ATI) will study privacy concerns unique to telemedicine practitioners. A national meeting is scheduled for October 2002. Using feedback from the OAT grantees, ATI's preliminary research showed that other specific privacy issues related to telemedicine practice are:

- The presence of outsiders or non-clinical persons in teleconsultations (e.g. non-clinical technicians, camera people and schedulers located on either side of a telemedicine consultation or at the site of a service provider, either physically or via the technology they support)
- Clinical Personnel who may not be visible or observable by the patient may also be involved in a teleconsultation
- Patient information routinely stored electronically and/or physically at each site may not be protected by policies or procedures as effectively as information used in on-site encounters.

Kumekawa also raises other provocative questions on telemedicine and privacy: *What should be done with the videotape of the consultation? How should Internet transmissions of identifiable information be handled? What types of privacy contracts should be made between the non-health staff and the practitioner? Can E-mail information be de-identified when part of the file includes scanned photos or video?* These and other equally important issues will be discussed by experts at the October 2002 meeting. The Commonwealth of Virginia should participate, or follow closely the implications for telemedicine put forward by these experts. Also, there needs to be a legal analysis of these policy implications at either the VHD level, or at the State Attorney General level.

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[67] Kumekawa, Joanne K. (September 30, 2001). "Health Information Privacy Protection: Crisis or Common Sense?" *Online Journal of Issues in Nursing*. Vol. #6 No. #3, Manuscript 2. Available: http://www.nursingworld.org/ojin/topic16/tpc16_2.htm.

HIPPA – Privacy Rule Compliance Model

Taking into account the administrative activities required by the Privacy rule, organizations and consultants suggest several necessary steps that health care entities should follow to ensure compliance. A model compiled from multiple sources is presented below.

- Identify a Privacy Officer and possible an implementation team. Among the activities recommended for this team are:
    - Analyze and understand HIPAA, the *Privacy* rule and its relationship with other provisions (e.g. the *Transaction* rule, the *Security* rule), and other federal legislations.
    - Analyze and understand any specific state law, especially if the confidentiality state laws are preempted by HIPAA.
    - Educate the organization's leadership and establish the entity's privacy ethics.
    - Conduct an assessment of existing practices of PHI transmission.
    - Develop budgets and timelines to ensure HIPAA/Privacy rule compliance by the deadline.
- Develop the entity's Privacy Policies and Procedures.
    - Train employees to assure a better understanding of HIPAA/Privacy requirements, internal policies and procedures, benefits for patients and institution, compliance incentives and violations.
    - Organize the flow of documents.
    - Establish storage solutions for files containing procedures, patient authorizations, and acknowledgement forms.
- Identify business associates and include privacy provisions in the renewed contracts. The HHS model can be used in part, as a whole, or replaced by a different language that conveys a similar message.

Establish an on-going review of forms, policies, procedures, technology, and information flows, to identify the need for revisions. Reward employees for suggesting measures that would increase compliance with the Privacy rule.

8.12 Appendix L. DMAS Telemedicine Billing Codes

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Commonwealth of Virginia September 16, 2002

DMAS Telemedicine Billing Code	Description:	DMAS Payment for adults	Comments:
Y0200	consultation, typically 15 minutes	$35.50	corresponds to CPT 99241
Y0201	consultation, typically 30 minutes	$51.31	corresponds to CPT 99242
Y0202	consultation, typically 40 minutes	$56.51	corresponds to CPT 99243
Y0203	echocardiography	$133.11	corresponds to CPT 93307
Y0204	echocardiography	$46.32	corresponds to CPT 93308
Y0205	doppler echo	$74.82	corresponds to CPT 93320
Y0206	doppler echo	$39.43	corresponds to CPT 93321
Y0207	doppler color flow	$76.47	corresponds to CPT 93325
Y0208	echography	$93.22	corresponds to CPT 76805
Y0209	echography	$185.98	corresponds to CPT 76810
Y0210	echocardiography fetal	$90.85	corresponds to CPT 76825
Y0211	EKG	$13.77	corresponds to CPT 93010
Y0212	Pharmacological management, minimum psychotherapy	$36.70	corresponds to CPT 90862. 90862 should no longer be used for telemedicine billing to DMAS
Y0213	consultation, typically 60 minutes	$115.10	corresponds to CPT 99244
Y0214	colposcopy	$57.03	corresponds to CPT 57452
Y0215	colposcopy with biopsy of the cervix and/or endocervical curretage	$73.69	corresponds to CPT 57454
Y0216	colposcopy with loop electrode excision procedure of the cervix	$132.02	corresponds to CPT 57460
Y0217	individual psychotherapy with medication management, 45-50 minutes	$71.61	corresponds to 90807
Y0218	individual psychotherapy with medication management, 75-80 minutes	$107.80	corresponds to 90809

8.13 Appendix M. Select Internet Data Sources

Evaluation Frameworks

The IOM report

- Available on-line at: http://www.nap.edu/catalog/5296.html

The ASPE/Lewin report

- Available on-line at: http://aspe.hhs.gov/search/health/reports/AAET/aaet.htm

U.S. Department of Justice *(National Institute of Justice)* and U.S. Department of Defense, Implementing Telemedicine in Correctional Facilities Report

- Available on-line at: http://www.ncjrs.org/pdffiles1/nij/190310.pdf

Department of Veterans Affairs, Telemedicine Strategic Planning Document

- The entire report is available on-line at: http://www.va.gov/publ/direc/health/notice/n9904.pdf

National Telecommunications and Information Administration – Technology Opportunities Program Evaluation Framework

- Available on-line at: http://www.ntia.doc.gov/top/research/HEALTH.pdf.

National standards and guidelines

The Food and Drug Administration (FDA) standards and guidelines:

- Guidance for the Submission of Premarket Notification for Medical Image Management Devices (2000) http://www.fda.gov/cdrh/ode/guidance/416.pdf.
- Guidance for Industry: Wireless Medical Telemetry Risks and Recommendations (2000) http://www.fda.gov/cdrh/comp/guidance/1173.html.
- FDA Talk Paper: FDA approves first digital mammography system. (2000) http://www.fda.gov/bbs/topics/ANSWERS/ANS01000.html.
- ODE: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. http://www.fda.gov/cdrh/ode/software.pdf.
- MQSA Regulations relevant to new mammographic modalities are in 21CFR900: Quality Mammography Standards http://www.fda.gov/cdrh/mammography/frmamcom2.html#12

Center for Disease Control (CDC) – the National Electronic Disease Surveillance System (NEDSS)

- http://www.cdc.gov/programs/research12.htm

Recommended standards and guidelines

HHS technology guidelines

- Available on-line at: http://telehealth.hrsa.gov/pubs/tech/chapter3.htm

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
http://www.jcaho.org/accredited+organizations/hospitals/standards/revisions/2001/medical+staff.htm#four.

Clinical Guidelines

- *Agency for Healthcare Research and Quality* – in cooperation with the American Medical Association and the American Association of Health Plans sponsors the National Guideline Clearinghouse, a compilation of evidence-based clinical guidelines - http://www.guideline.gov/index.asp
- *American Academy of Ambulatory Care Nursing* - Telehealth Nursing Practice Administration & Practice Standards - http://www.aaacn.org/resource/teleheal.htm#3
- *American Academy of Dermatology* – Guidelines for telemedicine dermatology services - http://www.aadassociation.org/telemedicine.html.
- *American College of Radiology* - Standard for Teleradiology - http://www.acr.org/cgi-bin/fr?tmpl:standards02,pdf:pdf/teleradiology.pdf
- *American Psychiatric Association* - Resources on Telepsychiatry - http://www.psych.org/pract_of_psych/tp_paper.cfm
- *American Psychological Association* - Services By Telephone - http://www.apa.org/ethics/stmnt01.html
- *The American Nurses Association* - Core Principles on Telehealth - http://www.nurse.org/acnp/telehealth/th.ana.core.shtml
- *The American Telemedicine Association* - Telehomecare clinical guidelines - http://www.atmeda.org/search/search.htm
- *University of Pittsburg Medical Center* - Clinical and technical guidelines for Telepathology - http://telepathology.upmc.edu/

Agency for Healthcare Research and Quality (AHRQ) evaluation of clinical services (cost-benefit analyses) – Evidence Reports

- Telemedicine for the Medicare Population
  http://hstat.nlm.nih.gov/hq/Hquest/screen/DirectAccess/db/3635

- Telemedicine, Supplement: Indirect Home Interventions
  http://hstat2.nlm.nih.gov/hq/Hquest/db/3636/screen/DocTitle/odas/1/s/55058