Telemedicine: An Important Force in the Transformation of Healthcare

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Acknowledgements

EXECUTIVE SUMMARY

TELEMEDICINE is a broad term within Health Information Technology ("Health IT") that encompasses methods for electronically transmitting medical information to sustain and/or improve a patient's health status. These methods can include: store-and-forward technology for documents and images; remote monitoring of a patient's vital signs; secure messaging; e-mail exchange of data, alerts and reminders between physicians and patients; and the ability to observe, diagnose and recommend treatment via videoconference.

There are multiple products and services and respective industries that are involved in developing the various applications of telemedicine, including information technology vendors, medical device manufacturers, pharmacies, hospitals, nursing homes, and venture capitalists, among others.

In the current environment of a shortage of healthcare professionals, greater incidence of chronic conditions, and rising healthcare costs, telemedicine offers a potential tool to improve efficiency in the delivery of healthcare.

The need for telemedicine is further compounded by the following factors:

- Significant increase in the U.S. population—estimated growth of 20 percent (to 363 million) between 2008-2030
- Shortage of healthcare professionals being educated, trained and licensed
- Increasing incidence of chronic diseases around the world, including diabetes, congestive heart failure and obstructive pulmonary disease
- Need for efficient care of the elderly, home-bound, and physically challenged patients
- Lack of specialists and health facilities in rural areas
- Adverse events, injuries and illness at hospitals and physician's offices
- Need to improve community and population health

Telemedicine can play an important role in providing solutions to these challenges. For instance, telemedicine maximizes the use of existing health care professionals by allowing them to remotely diagnose, monitor and recommend treatment for patients located in rural areas. In addition, telemedicine limits patient exposure to infections by eliminating or limiting the need to visit a hospital or a physician's office for healthcare services.

Despite these potential benefits, there are a number of barriers that have hindered the expansion of telemedicine in the U.S. market, including:

- Reimbursement policies of third party payers
- Concerns about security and privacy
- Lack of common standards and certification decreasing the likelihood of interoperability between medical devices, videoconferencing and other systems
- Limited availability of broadband Internet, medical access and education, especially in rural and underserved areas
- Medical liability and malpractice issues
- Variable and exclusive state licensure requirements
- Mismatch of telemedicine costs and benefits between physicians and insurers
- Limited Congressional funding for telemedicine[1]

These barriers must be sufficiently overcome to accelerate the development and application of telemedicine.

The U.S. Department of Commerce (DOC) can play an important role in addressing these barriers in light of its current relationship and knowledge of the relevant industries that collaborate to deliver telemedicine products and services, while expanding DOC relationships with relevant stakeholders.

Although limited statistics on the telemedicine sector exist, available data points give some idea as to the sector's potential. A recent presentation to the American Telemedicine Association (ATA) estimated the 2007 market size of the "Home Telehealth and Remote Patient Monitoring" sector at $600 million.[2] Two market research studies released in 2008 indicated that the market for telemedicine devices

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[1] Under a telemedicine grant program, between October 1, 2006 through September 30, 2008, HHS' Health Resources and Services Administration (HRSA) has administered 93 telemedicine/telehealth projects, 24 of which received $6.1 million in funding (Office for the Advancement of Telehealth, "Grantee Profiles 2007-2008," p. 2) The signing of the American Recovery and Reinvestment Act (ARRA) on February 17, 2009, appropriated approximately $19 billion for Health IT. However, the only specific funding reference to telemedicine appears under the $2.5 billion appropriation for a "distance learning, telemedicine and broadband program" under the 1936 Rural Electrification Act (American Recovery and Reinvestment Act of 2009, p.4).

[2] From speech by Sunil Harazay of Bayer Health Care at ATA Mid-Year meeting, September 16, 2008.

and services is forecast to exceed $1.8 billion by the year 2013[3] and that the market is expected to grow at a five-year compound annual growth rate of 56 percent.[4]

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[3] "Telemedicine Revenues to Exceed $1.8 Billion by 2013, Report Projects." Marketwire, July 23, 2008; report available through http://www.pf.com/marketResearchPDInd.asp?repId=608.

[4] Chang, Christine. "Intel's Health Guide Puts Telehealth in the Spotlight (Analyst's Opinion)," Datamonitor, November 13, 2008.

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I.   Introduction—Broad Description of Telemedicine

There are many factors, such as a shortage of healthcare professionals and greater incidence of chronic conditions that are driving the need to develop tools and solutions to improve healthcare delivery. One possible tool is the electronic exchange of medical information, which is commonly referred to as Health Information Technology ("Health IT").   Health IT plays a key role in digitizing and transmitting health information electronically that can improve patient outcomes. Health IT processes can also include:

1) Use of electronic health records (for patients, physicians, insurers, hospitals and clinics);
2) Health information exchange across industries and geographies;
3) Use of electronic health information to detect trends in population and public health; and
4) Transmission of medication refills and a patient's prescription history.

A key part of Health IT is increasing the frequency and use of technology-driven remote monitoring and consultation to treat patients. This area of Health IT is commonly referred to as "telemedicine." There is no universally accepted definition of telemedicine; however, the American Telemedicine Association (ATA), a leading trade association, defines the term as follows:

> Telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve patients' health status. Closely associated with telemedicine is the term 'telehealth,' which is often used to encompass a broader definition of remote healthcare that does not always involve clinical services. Videoconferencing, transmission of still images, e-health including patient portals, remote monitoring of vital signs, continuing medical education and nursing call centers are all considered part of telemedicine and telehealth.[5]

Although limited data presently exists regarding the telemedicine sector, available statistics hint at its potential. A recent presentation to the

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[5] Information is from the American Telemedicine Association website, (www.americantelemed.org).

American Telemedicine Association (ATA) estimated the 2007 market size of the "Home Telehealth and Remote Patient Monitoring" sector at $600 million.[6] Separate research studies released in 2008 indicated that the market for telemedicine devices and services is forecast to exceed $1.8 billion by 2013[7] and that the market is expected to grow at a five-year compound annual growth rate of 56 percent.[8] ATA also reported that there are approximately 200 U.S. telemedicine networks linking 3,000 sites, and 80,000 homes have been wired for remote healthcare monitoring.[9]

II.   Products and Services Within the Telemedicine Sector

Telemedicine involves a combination of medical products and services.[10] Accordingly, there are numerous products and services comprising telemedicine, ranging from medical devices to delivery systems.

Products: Many medical devices capable of collecting and electronically transmitting information (either immediately or in the future) can be digitized to be used in telemedicine applications. These include blood glucose meters, pulse oximeters, blood pressure cuffs, CT scanners, and MRI machines. Some of these devices are targeted towards home healthcare and the needs/wants of patients interested in closely monitoring their health status, while others facilitate the exchange of information between hospitals, clinics and physicians.

Key industry associations and stakeholders involved in these types of products include the Advanced Medical Technology Association (AdvaMed), the Medical Industry Technology Alliance (MITA), and the Medical Device Manufacturers Association (MDMA).

Services: The use of medical products with electronic exchange capabilities allows for the provision of a wide range of telemedicine-related services. These include store-and-forward technology for documents and images; remote monitoring of a

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[6] From speech by Sunil Harazay of Bayer Health Care at ATA Mid-Year meeting, September 16, 2008.

[7] "Telemedicine Revenues to Exceed $1.8 Billion by 2013, Report Projects." Marketwire, July 23, 2008; report available through http://www.pf.com/marketResearchPDInd.asp?repId=608.

[8] Chang, Christine. "Intel's Health Guide Puts Telehealth in the Spotlight (Analyst's Opinion)," Datamonitor, November 13, 2008.

[9] From remarks by Jonathan Linkous of ATA at the ATA Mid-Year meeting, September 16, 2008.

[10] This paper will refer to "products and services" when describing vendor offerings in the telemedicine sector.

patient's vital signs; secure messaging; e-mail exchange of data, alerts and reminders between physicians and patients; and having a specialist remotely available by videoconference to observe and diagnose a patient's condition and recommend treatment. Electronic exchange of prescription information between physicians, pharmacies and consumers is an additional service. Other telemedicine services include transmitting information to alert communities about pandemics and other widespread health threats.

The key trade associations and stakeholders involved in telemedicine services include the American Telemedicine Association (ATA), the Healthcare Information and Management Systems Society (HIMSS), and the American Health Information Management Association (AHIMA).

The availability of innovative medical products and new applications of existing products and services can enhance the application of telemedicine.[11] For example, more frequent information exchange of basic personal information remotely, including glucose level, pulse rate and heart rate can lead to improved health for many patients, especially those with chronic conditions.

III.   Potential Benefits of Telemedicine

There are several benefits that can be realized by an increased use of telemedicine and there are multiple factors driving the need for telemedicine. Benefits can range from increased compliance in taking medications, to improved healthcare delivery in rural and underserved areas, to improved delivery of healthcare services outside hospitals and clinics, and better utilization of healthcare professionals.

Manage chronic diseases effectively: Chronic conditions such as diabetes, congestive heart failure, and obstructive pulmonary disease require long-term treatment, and use of multiple specialists, all of which significantly increase costs. These patients account for roughly 75 percent of total healthcare expenditures.[12] Widespread telemedicine adoption will allow vital sign information and monitoring to be gathered frequently (instead of only during periodic physician visits). Messages can then be simultaneously transmitted to the treatment team,

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[11] According to the Census Bureau, the U.S. population is expected to increase by 60 million (20 percent) between 2008 and 2030. "Table 1a, Projected Population of the United States, by Race and Hispanic Origin, 2000 to 2050," U.S. Interim Projections by Age, Sex, Race and Hispanic Origin, U.S. Census Bureau, March 2004.

[12] Max E. Strachura, MD and Elena V. Khasanshina, MD, PhD. "Telehomecare and Remote Monitoring: An Outcomes Overview," published by the Advanced Medical Technology Association (AdvaMed); October 2007.

allowing for possible early intervention (a physician or hospital visit) if a patient's condition deteriorates.

Improve care of elderly, home-bound, and physically challenged patients: Use of telemedicine to reduce the frequency of visits to physician offices and hospital emergency rooms can potentially lead to greater convenience and compliance for elderly and home-based patients. By reducing the frequency of visits by remote monitoring and e-mail information exchange, more timely patient intervention can occur before acute care treatment is necessary.

Empower patients regarding their own health: Raising the responsibility level of patients to take their medicines and report basic health metrics to their physician(s) by using telemedicine represents an opportunity for patients and caregivers to play a greater role in their own care. By giving the patient the ability to directly see the correlation between adherence to treatment regimen and improvement in health, patients will more likely comply with treatment protocols, leading to faster recovery.

Improve competitiveness of U.S. industry by controlling healthcare costs: With rising healthcare costs,[13] telemedicine can provide a tool for companies and insurers to better control and manage healthcare spending[14] by enabling greater use of remote monitoring of a patient's condition to minimize the need for acute care intervention, and more efficient deployment of healthcare professionals (discussed further below).

Improve community and population health: Electronic sharing of images and video consults, a component of telemedicine, permits easier exchange of information between public health services about a rare or unusual health condition, better measure chronic disease in a population, or address a public health crisis such as pandemic flu or anthrax. Faster awareness of current threats will help public health providers make better decisions regarding population health in these situations.

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[13] In 2006, average U.S. healthcare expenditures reached $7,026/person, totaling $2.1 trillion and accounting for 16 percent of U.S. Gross Domestic Product (GDP). "National Health Expenditures by Type of Service and Source of Funds, CY 1960-2006"; Center for Medicare and Medicaid Services, www.cms.hhs.gov/NationalHealthExpendData/, published January 2008.

[14] The Congressional Budget Office estimates that, without changes in law, healthcare spending will rise to 25 percent of GDP by 2025. Peter R. Orszag, Congressional Budget Office, "Growth in Health Care Costs," Testimony to Committee on the Budget, U.S. Senate, January 31, 2008, p. 3.

Source of creative, innovative employment within healthcare sector: Venture capital (VC) firms have shown increasing interest in the medical device sector in recent years, with 2007 investment in the sector reaching an all-time record of $3.9 billion, up 39.6 percent compared with 2006.[15] Enhancing VC awareness of potential new telemedicine applications for medical devices could further advance the prospects for companies across the medical device and related industries.

Address possible future shortages of healthcare professionals:[16] Telemedicine services, such as videoconferencing and remote consults, better utilize current staff,[17] whether at a hospital, physician's office, or via home-care. The availability of telemedicine technologies and procedures[18] can also alleviate potential shortages of healthcare professionals by enabling remote consultations by physicians and nurses for patients located in other states or countries.[19]

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[15] Report is available at
https://www.pwcmoneytree.com/MTPublic/ns/moneytree/filesource/exhibits/National_MoneyTree_full_year_Q4_2007_Final.pdf.

[16] Some of the pending health professional shortages are due to limited openings in education programs, but upcoming retirements, a desire by some professionals to balance their work and home lives, and difficulty in retaining current staff, are also factors. The nursing deficit is forecast to worsen even though the Bureau of Labor Statistics predicts nursing will be one of the fastest growing occupations in the coming years, generating approximately 587,000 net new jobs between 2006 and 2016. "Better Late Than Never: Workforce Supply Implications of Later Entry into Nursing," *Health Affairs*, January/February 2007, p. 183, and "Registered Nurses," U.S. Department of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, 2008-2009 Edition, http://www.bls.gov/oco/ocos083.htm.

[17] In 2006, the Association of American Medical Colleges reported there will likely be a shortage of at least 100,000 physicians in the next 20 years, while the ongoing nurses shortage is expected to reach 340,000 by 2020, three times larger than any previous deficit. The nursing deficit is forecast to worsen despite a Bureau of Labor Statistics prediction that nursing will be one of the fastest growing occupations, generating approximately 587,000 net new jobs between 2006 and 2016. Some of the pending health professional shortages are due to limited openings in education programs, but upcoming retirements, a desire by some professionals to balance their work and home lives, and difficulty in retaining current staff, are also factors. "Position Statement on the American Workforce," Association of American Medical Colleges, http://www.aamc.org/workforce/workforceposition.pdf, June 2006; "Better Late Than Never: Workforce Supply Implications of Later Entry into Nursing," *Health Affairs*, January/February 2007, p. 183; and "Registered Nurses," U.S. Department of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, 2008-2009 Edition, http://www.bls.gov/oco/ocos083.htm.

[18] This paper will use the terms "technology" and "procedure" to describe telemedicine activities not specifically tied to vendor products or services (see footnote 2).

[19] For example, from 2001 to 2005, Partners Telemedicine conducted a pilot telemedicine program called Operation Village Health in a region of northern Cambodia. Partners collaborated with two non-profit organizations to send a nurse to the region every month with a digital camera and basic medical equipment. The nurse collected information at a clinic and, after obtaining patient consent and transcribing medical assessments into English, sent e-mails (including images) to Partners and a local non-profit. E-mail replies were sent out within 12 hours of initial receipt. Paul J Heinzelmann, Gary Jacques, and Joseph C Kvedar, "Telemedicine by E-Mail in Remote Cambodia," Journal of Telemedicine and Telecare 2005; 11 (Suppl. 2): S2:44–47. In addition, Australia's Center for Online Health sponsors the England-based Swinfen Charitable Trust (http://www.uq.edu.au/swinfen), which uses e-mail to transmit health information and digital pictures between

Reduce deaths, injuries, and infections: Increased use of telemedicine across all settings could reduce the incidence of adverse events caused by treatment and medication errors[20] arising from piecemeal or inaccurate patient information, leading to more consistent patient treatment by limiting the number of hospital visits and reducing exposure to illness from other patients. In addition, electronic prescribing can help reduce errors in dispensing medicines by eliminating the need to decipher handwritten prescriptions.

Extend reach to underserved/rural communities in the United States: Many regions of the United States (both urban and rural) do not have a full range of healthcare services available. The presence of telemedicine services in rural areas[21] has been shown to improve care by decreasing transportation costs; more efficiently deploying healthcare professionals and specialists; and offering timely healthcare delivery without the obstacles presented by lakes, forests and mountains.[22]

IV.   Challenges to Telemedicine

The telemedicine sector currently faces a number of challenges and barriers. This partly stems from healthcare providers having greater interest in using Health IT to implement electronic health records (EHRs) and reduce administrative costs rather than use these technologies to make more healthcare-related services widely available.[23] The root cause of this limited application seems to be the financial

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specialists willing to give free advice and 118 hospitals in 34 countries (such as Bangladesh, Nepal, and Iraq) serving the poor, sick and disabled.

[20] A widely quoted 2000 Institute of Medicine (IOM) study estimated that 44,000 to 98,000 hospital deaths and half of all adverse reactions to medicines each year were caused by preventable medical errors. It should be noted that the IOM report understates the medical error problem (since the study focused entirely on hospitals), as adverse events also occur in physician's offices, clinics, nursing homes, and outpatient surgical centers. L. T. Kohn, J. M. Corrigan, and M. S. Donaldson, eds. "To Err Is Human: Building a Safer Health System." Institute of Medicine of the National Academies, 2000, Washington, D.C: National Academy Press, Tamar Nordenberg, "Make No Mistake: Medical Errors Can Be Deadly Serious," FDA Consumer Magazine, September/October 2000, and Lucian L. Leape and Donald M. Berwick; **"**Five Years After *To Err Is Human*: What Have We Learned?" JAMA, May 18**,** 2005; 293: 2384 – 2390.

[21] In 2002, approximately 65 million (22.5 percent) of Americans lived in rural areas; this number varies by source and definition used for rural; figure from http://ruralhealth.hrsa.gov/initiative.htm.

[22] ATA 2007 white paper showing telemedicine's benefits in underserved communities: http://www.americantelemed.org/news/Whitepapers/Telehealth%20and%20the%20Provider%20Shortage.pdf

[23] EHRs can assist the application of telemedicine by consolidating a patient's records in a central location. However, this is distinct from the additional services offered by telemedicine. More attention should be given to the availability of telemedicine services apart from their use in EHRs.

investment that is needed for full development and, more importantly, the lack of adequate reimbursement opportunities for such investment. In addition, there are several other barriers that have slowed the development of telemedicine, including[24]:

- Reimbursement policies of third party payers
- Concerns about security and privacy
- Lack of common standards and certification decreasing the likelihood of interoperability between medical devices, videoconferencing and other systems
- Availability of broadband Internet, medical access and education, especially in rural and underserved areas
- Medical liability and malpractice issues
- Variable and exclusive state licensure requirements
- Mismatch of telemedicine costs and benefits between physicians and insurers
- Limited Congressional funding for telemedicine[25]

Reimbursement policies of third party payers: The business case for widespread adoption of telemedicine presently depends upon obtaining satisfactory reimbursement from one of three primary sources: 1) the Department of Health and Human Services' (HHS) Centers for Medicare and Medicaid Services (CMS)[26]; 2) State-level Medicare contractors; and 3) Private insurers. All three payers play an important role in reimbursement of telemedicine applications.

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[24] "Innovation, Demand and Investment in Telehealth," Technology Administration, U.S. Department of Commerce, 2004, http://www.atp.nist.gov/eao/innovation_demand_invest_telehealth_022004.pdf, pp. 70-91.

[25] Under a telemedicine grant program, between October 1, 2006 through September 30, 2008, HHS' Health Resources and Services Administration (HRSA) has administered 93 telemedicine/telehealth projects, 24 of which received $6.1 million in funding (Office for the Advancement of Telehealth, "Grantee Profiles 2007-2008," p. 2) The signing of the American Recovery and Reinvestment Act (ARRA) on February 17, 2009, appropriated approximately $19 billion for Health IT. However, the only specific funding reference to telemedicine appears under the $2.5 billion appropriation for a "distance learning, telemedicine and broadband program" under the 1936 Rural Electrification Act (American Recovery and Reinvestment Act of 2009, p.4).

[26] The U.S. Food and Drug Administration (FDA) also plays an important role in reimbursement, as the regulatory agency responsible for approving many medical devices and pharmaceuticals. FDA must approve a product before CMS can make a reimbursement decision. FDA appears to be considering whether some Health IT hardware and software will first require marketing approval as medical devices. Telemedicine hardware and software vendors will need to closely watch this topic, as regulation (whether by the FDA or another government agency) would likely become another barrier to wider adoption of these products and services. Storey, David D. "A Closer Look at Telemedicine's Legal Issues," HHN Most Wired Magazine, April 30, 2008.

CMS: Selected CMS statistics show the shares of public sector healthcare expenditures[27]:

2006 National Healthcare Expenditures=$2.106 billion; 46% of expenditures from public sector

74% of 2006 public spending came from CMS programs:
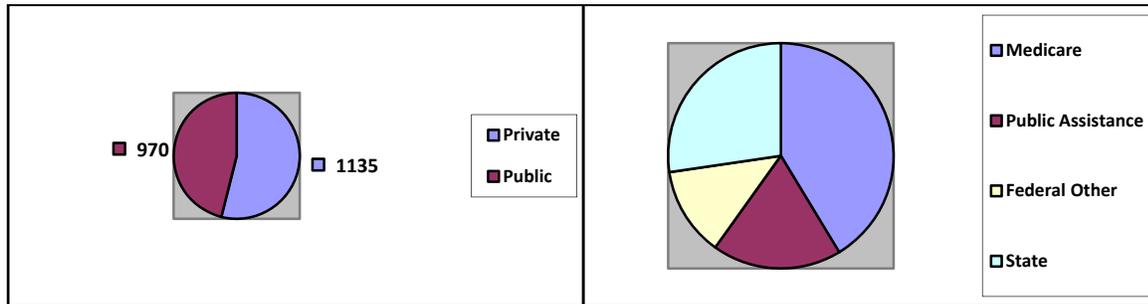
CMS' decision to reimburse plays an important role in determining widespread adoption and acceptance of a particular product or service. This is partly due to the complex "coding" system used by CMS to reimburse for medical procedures and treatments.

In addition, CMS tends to cover a technology or procedure only if it benefits patients covered by their programs (those over 65 in Medicare,[28] and low-income patients in Medicaid)[29], and the technology or procedure can demonstrate that it is "reasonable and necessary" to sustain or improve patient treatment. Accordingly, this limits the availability of federal funding available for applications of telemedicine outside of the designated age and/or poverty groups.

These problems are exacerbated by the preference within the CMS system to reimburse based upon face-to-face physician/patient encounters.[30] As noted,

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[27] "National Health Expenditures by Type of Service and Source of Funds, CY 1960-2006;" see footnote 4.

[28] ATA published a 2006 policy paper about Medicare telemedicine reimbursement policy; report is available at http://www.americantelemed.org/news/Medicare%20Payment%20Of%20Services.pdf.

[29] The age group and poverty level limitations imposed by Congress on the Medicare and Medicaid programs compound the obstacles faced by the telemedicine industry in seeking an appropriate level of reimbursement for their respective products and services.

[30] CMS does cover a limited range of telemedicine procedures. CMS covers teleradiology (where, from a remote location, a specialist can review electronically transmitted "radiographic patient images and consultative text"), as well as analysis of images using either store-and-forward technology or "real-time" consultation. Medicare state-level contractors, Medicaid, and private insurers also cover some telemedicine applications, although these vary by jurisdiction. Teleradiology definition from the University of Iowa Hospitals and Clinics, Department of Radiology website: http://www.radiology.uiowa.edu/MoreRAD/Teleradiology/Tele.html.

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telemedicine ultimately reduces the occurrence of in-person treatment, and therefore are disadvantaged under this CMS policy.

Further, since CMS reimbursement for telemedicine applications has been less than optimal to date, companies and providers have been cautious about implementing telemedicine products and services, instead testing small-scale, pilot projects usually funded by grant money. These projects require significant time and resources to identify, design, and implement, and without certainty of payment for the new services, there is a disincentive to commence these initiatives. There is a need for large-scale studies demonstrating the cost-effectiveness and treatment benefits of telemedicine. Pilot projects alone are not sufficient.

The preference of the CMS system to reimburse based upon face-to-face physician/patient encounters, coupled with a complex claims "coding" system that offers different payments for the same treatment based upon location and services provided, present many challenges for vendors trying to receive sufficient payment for their telemedicine products and services. These challenges have cumulatively resulted in limited opportunities for the telemedicine sector to flourish and expand.

State: State-level contractors make the majority (up to 90 percent) of Medicare coverage and reimbursement decisions.[31] Companies with new products or services often apply first for state-level coverage, primarily because if a contractor covers the product or service, the company then receives a return on their investment, possibly leading later to a favorable CMS coverage and/or reimbursement decision. Companies may alternatively seek CMS coverage if state-level contractors either reject coverage, or give insufficient reimbursement. However, if CMS rejects a technology or procedure, the state-level contractor option no longer exists. An important complication of this arrangement is that due to contract language limitations, CMS cannot exchange coverage and reimbursement information with state-level contractors. As a result, the barrier created by the prohibition of information exchange between CMS and state-level contractors hinders the diffusion and adoption of innovative new technologies (such as those found in telemedicine) by companies across the healthcare sector.

Private: Private insurers and tools such as health maintenance organizations (HMOs) also play an important role in deciding reimbursement, and at what level. In 2006, ATA published a white paper showing trends in private payer

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[31] Phurrough, M.D., Steven, "Medicare: National Coverage Determinations," PowerPoint presentation, Regulatory Affairs Professional Society conference, October 18, 2006.

reimbursement,[32] which showed that over 100 private payers are reimbursing for selected telemedicine services, but the paper's main message is that the "United States is progressing towards more private reimbursement for telemedicine services, but at a disappointingly slow pace."[33]

Private payers are developing quality and effectiveness measures to show which technologies and procedures are effective in improving patient treatment. Typically, clinical data is reviewed and analyzed to determine quality and effectiveness. The quality and effectiveness of telemedicine cannot be judged solely by analyzing clinical data. Instead, telemedicine often involves multiple care delivery products and services that often occur outside clinical environments (such as hospitals, physician offices, and even at a patient's own home). In addition, telemedicine poses unique challenges in measuring benefits (e.g., quantitatively measuring better patient outcomes).

Concerns about Security and Privacy: When examining the privacy and security aspects of telemedicine, the Health Insurance Portability and Accountability Act (HIPAA) is an important part of the discussion. HIPAA is a technical, complex statute signed by President Clinton in 1996 that has been in full effect since 2003. HIPAA regulations cover three broad areas: administrative simplification of handling electronic health records, privacy of individually identifiable health information, and security.[34] As a result, HIPAA influences diverse topics such as electronic health transactions, information exchange, data privacy and data security, as well as "traditional" in-person health consultations.

Although the healthcare industry has followed HIPAA's regulations for several years, the Health IT and telemedicine sectors have evolved since HIPAA became law. As a result, it is unclear how (and whether) the current regulations protect electronic information exchange,[35] and by extension, telemedicine applications. It

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[32] Whitten, Pamela Ph.D., and Laurie Buis, M.S.I., "Private Payer Reimbursement for Telemedicine in the United States." Michigan State University, 2006; report is available at (http://www.americantelemed.org/news/Whitepapers/2006%20Private%20Payer%20Report.pdf,

[33] Ibid, page 2.

[34] Michael F. Chiang, M.D., and Justin Starren, M.D., Ph.D., "Data Confidentiality and HIPAA" Chapter; "Home Telemedicine for the Health Care Provider: A Practical Guide;" Informatics for Diabetes Education and Telemedicine (IDEAtel) pilot project.

[35] In December 2008, HHS published the "National Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information," along with a "Health IT Privacy and Security Toolkit," representing initial steps in providing some principles regarding HIPAA's application to Health IT. Additional material and guidance documents have been promised for future release. Link to the Framework is available at http://www.hhs.gov/healthit/privacy/framework.html.

appears that most parties involved in HIPAA's passage (including industry, Congress, and regulators) are reluctant to amend the statute to reflect changes in the overall healthcare sector, even though privacy and security concerns about electronic health transactions have been voiced by many parties, including patient advocacy groups such as the Patients Privacy Rights Foundation, consumers,[36] and the General Accountability Office.[37] This has occurred because HIPAA represents a "floor" in terms of data privacy and security protection (as states can impose more stringent requirements).[38] If current regulations do not sufficiently protect electronic healthcare information exchange, telemedicine companies may need to persuade lawmakers and regulators to reexamine HIPAA's provisions and make appropriate amendments.[39]

Lack of common standards and certification decreasing the likelihood that medical devices, videoconferencing and other systems will be interoperable:
Availability of systems and infrastructure possessing sufficient capacity to gather and exchange data, images and other health information is necessary for effective use of telemedicine services. As noted, telemedicine involves the intersection between products and services; accordingly, the seamless exchange of information and data (often called "interoperability") between medical devices, communication systems and infrastructure is essential. This presents telemedicine with a major barrier, as current use of hardware and software using interoperable technology creates information "islands" that cannot exchange or process data with each other, complicating the sharing of health information between hospitals, physicians, providers and patients.

The standards community (through the Health Information Technology Standards Panel—HITSP, organized under the American National Standards Institute and explained further below) is in the process of determining how to make these technologies and procedures truly interoperable.[40] However, the process involved is time-consuming, and also requires resolving possible "gaps" between already

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[36] Results of polls listed at the Electronic Privacy Information Center; http://epic.org/privacy/medical/polls.html

[37] "Health Information Technology: Efforts Continue but Comprehensive Privacy Approach Needed for National Strategy," issued June 19, 2007 http://www.gao.gov/new.items/d07988t.pdf

[38] Chiang and Starren, Ibid. Fact sheets showing HIPAA provisions and regulations that impact consumers, hospitals, and health plans, can be obtained from the HHS' Office of Civil Rights website at www.hhs.gov/ocr/hipaa.

[39] ARRA does not make significant amendments to HIPAA with respect to notification requirements and penalties for wrongful disclosures and privacy breaches in personal health records.

[40] ARRA includes a provision establishing an HHS Health IT Standards Committee; HITSP will be collaborating with the new HHS Standards Committee to further develop standards for exchange of health information.

agreed-upon standards (and sometimes choosing between competing standards) in order to ensure that the infrastructure works seamlessly.

Limited availability of broadband Internet, medical access and education, especially in rural and underserved areas: Approximately 65 million U.S. citizens live in rural areas and lack ready access to physicians and specialists that can address any special healthcare needs. The absence of broadband Internet access (especially in rural and poorer urban areas) has hindered the use of telemedicine in these settings.

The U.S. government (through the FCC and Department of Agriculture[41]) has programs to facilitate broadband Internet service to underserved communities where infrastructure costs might otherwise be exorbitant. The largest of these programs, introduced in November 2007 by the FCC, grants more than $400 million to underserved communities, with a specific healthcare focus.[42] However, the grants allocated under this program over a three-year period are generally small (only 14 of 69 grant applicants would receive support of greater than $10 million),[43] and will only cover a portion of the underserved communities and regions.[44]

Medical liability and malpractice issues: Multiple parties play a role in the transmission and execution of telemedicine. As a result, if an error occurs during a health application using telemedicine, it is unclear which health professional bears responsibility. In addition, if communication is lost during the consultation or procedure, would the power company or telecommunications firm be liable? These legal issues (among others) have not been addressed to date. Accordingly, liability concerns continue to be a barrier to full acceptance of telemedicine.

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[41] Press Release: "USDA Awards More Than $22.3 Million for Distance Learning and Telemedicine Grants," http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1RD?printable=true&contentidonly=true&contentid=2007/10/0275.xml. USDA, through the Rural Development initiative, has a Distance Learning and Telemedicine grant program, which awarded $22.3 million to 78 recipients in October 2007 (as well as a loan program). These grants focus on increasing medical access in rural areas while providing greater educational opportunities for hospitals, providers, and citizens, with the goal to "increase economic opportunity and improve the quality of life for rural residents."

[42] "FCC Launches Initiative to Increase Access to Health Care in Rural America Through Broadband Telehealth Services," Press Release, November 16, 2007; http://www.fcc.gov/wcb/tapd/ruralhealth/.

[43] "Rural Health Care Pilot Program Applicants," November 16, 2007; Ibid.

[44] With respect to supplemental expenditures to address the current lack of broadband availability, there are initiatives underway. The 2009 American Recovery and Reinvestment Act appropriated $4.7 billion for the new National Telecommunications and Information Administration (NTIA) Broadband Technology Opportunities Program, and an additional $2.5 billion for the USDA Distance Learning and Telemedicine grant program. $4.37 billion of the NTIA money is specifically targeted for deploying broadband in underserved areas.

Variable and exclusive state licensure requirements: A major obstacle slowing adoption of telemedicine practices are state physician and nurse licensing[45] requirements,[46] and state regulations on e-mail and Internet exchange of patient treatment information. These restrictions affect the core concept of telemedicine: remote monitoring and healthcare delivery between patients and providers in different states.[47]

Reciprocal recognition of physician and nursing licenses is complicated by differing state requirements. Some reciprocity exists for physicians, but may be limited based upon the physician's specialization. Telemedicine licensure is a complicated issue for licensing boards when determining regulations overseeing this area, since they must consider jurisdiction, patient safety, and whether permitting these services might lead patients to seek treatment elsewhere. Currently, a patchwork of state rules exist governing telemedicine, including prohibition of telemedicine, to complete permission, to no guidance at all.[48]

In addition, "credentialing" (a process separate from licensure granting a physician the privilege to work at a hospital or clinic) represents a cultural barrier to increased telemedicine use. Disapproval of a physician's credentials by the on-site hospital reduces competition from out-of-area practitioners, preventing these physicians from practicing telemedicine because hospital administrators have never met them and/or have been unable to observe their work. The Joint Commission on the Accreditation of Healthcare Organizations is reviewing standards and requirements which could allow off-site physicians to provide hospital care.[49] As a result, the disparate licensing and credentialing requirements further hinder the use of telemedicine applications.

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[45] Some progress on licensure has occurred in nursing. According to the Bureau of Labor Statistics' 2008-2009 *Occupational Outlook Handbook* (footnote 8): "In all States…students must graduate from an approved nursing program and pass a national licensing examination…in order to obtain a nursing license. Nurses may be licensed in more than one State, either by examination or by the endorsement of a license issued by another State. The Nurse Licensure Compact Agreement allows a nurse who is licensed and permanently resides in one of the member States to practice in the other member States without obtaining additional licensure. In 2006, 20 states were members of the Compact, while 2 more were pending membership. All States require periodic renewal of licenses, which may require continuing education."

[46] A March 2007 ATA white paper outlines some key licensure issues; the report is available at: http://www.americantelemed.org/news/Whitepapers/Medical%20Licensure%20Portability%20Position.pdf.

[47] Phurrough, M.D., Steven, "Medicare: National Coverage Determinations," Ibid.

[48] "Innovation, Demand and Investment in Telehealth," U.S. Department of Commerce, February 2004, p. 84.

[49] http://www.jointcommission.org/AccreditationPrograms/Hospitals/Standards/FAQs/default.htm.

Mismatch of telemedicine costs and benefits between physicians and insurers:
Although physicians, hospitals, and clinics make the expenditures necessary to promote the use of telemedicine (e.g., design pilot projects, develop the hardware and software systems), insurers and payors are the primary financial beneficiaries of such practices. The cost/financial benefit mismatch may explain why "closed" systems (which act as both physician and insurer) like the Veterans Administration (VA)[50] and Kaiser Permanente have extensively used attributes of telemedicine such as EHRs while other systems have been slow to adopt. Potentially, if incentives were provided to physicians and hospitals, increased investment in hardware and software for telemedicine applications might result.

This is further supported by a 2006 survey conducted by Blumenthal in which physicians were asked about "major barriers" to adopting EHRs (these results could also apply to telemedicine). The survey indicates financial and capital investment needs, and making a convincing business case, are now prerequisites for physician adoption of EHRs. More than 80 percent of respondents cited "monetary incentives for purchase" and "additional payments" as reasons they were holding back from implementing EHRs in their practice (78 percent mentioned "protection from legal liability).[51]

Limited Congressional funding for telemedicine: Programs facilitating use of telemedicine have received limited Congressional funding to date. Congress has tried to codify the existence of the HHS Office of the National Coordinator (ONC) since President Bush created the office by executive order in 2004. However, these efforts were stymied during the 109th and 110th Congresses, in part due to disagreement about whether ONC is sufficiently committed to privacy and security in connection with health information exchange.[52] Congress reduced fiscal year 2008 Congressional funding for ONC well below the Bush administration's $118 million request to the 2007 figure of $61.3 million.[53] The reduced appropriations have limited the scope of ONC's grants and pilot projects for demonstrating the cost and treatment effectiveness of telemedicine applications, as well as testing networks and system architectures for exchanging information and transmitting services between remote sites.

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[50] The VA expects 50,000 patients to have remote monitors to engage in telemedicine services by 2009. Heuser, Stephen. "Telehealth Systems Slowly Gaining," Boston Globe, July 26, 2006.

[51] Blumenthal, David, "A National Survey of the Electronic Health Record Adoption in the United States," 19th AHIC Public Meeting, Washington, DC, January 22, 2008.

[52] ARRA codified the existence of ONC on February 17, 2009.

[53] "Federal healthcare IT funding cut short," Healthcare IT News, December 21, 2007.

The American Recovery and Reinvestment Act of 2009 appropriates approximately $19 billion towards the rollout of standards, certification and implementation of electronic health records in the United States, and the governance structures that will be necessary for widespread adoption. However, ARRA does not specifically target increased investment in telemedicine activities, except as a byproduct of the increased deployment of broadband Internet connections to areas either without coverage, or to underserved markets. Based upon existing information the utilization of telemedicine is not likely to enhance significantly under ARRA.

The U.S. Department of Commerce (DOC) can play an important role in addressing these barriers, using current relationships and knowledge about relevant industries that are collaborating to deliver telemedicine products and services. Commerce can help integrate differing points of view and develop consensus positions on issues of interest to the telemedicine sector, including reimbursement, standards and interoperability of medical devices, and privacy and security.

V. Potential Role of Manufacturers and Service Providers in Acceptance of Telemedicine

The barriers cited above have combined to prevent the full application and use of telemedicine. Some of these barriers can be removed administratively, while others will require resolution by legislative or regulatory means. U.S. manufacturers and service providers have two primary means by which they can influence acceptance and adoption of telemedicine:

Develop consistent technological and data standards for medical devices, electronic health records (EHRs) and information exchange: In the U.S., this effort has picked up momentum through the creation of two industry consortia, but many standards still need to be determined. HITSP (created in 2005) started the U.S. Health IT standards harmonization process, bringing together representatives from a wide range of trade associations and standards development organizations. HITSP's recent activities have addressed several standards related to telemedicine.[54] However, industry can assist HITSP and the Continua Health

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[54] HITSP's website: http://www.ansi.org/standards_activities/standards_boards_panels/hisb/hitsp.aspx?menuid=3.

Alliance[55] in identifying gaps in standards, creating standards as needed, and helping to select between competing standards, where appropriate.

<u>Involvement in Developing Policies for Telemedicine:</u> Telemedicine sector stakeholders have several opportunities to become more deeply involved in policy development affecting the industry. One of these routes is the National eHealth Collaborative[56] (formerly known as AHIC Successor, Inc), the follow-on group to America's Health Information Community (AHIC). HHS launched AHIC with the following charge:

> (AHIC) is a federal advisory body, chartered in 2005 to make recommendations to the Secretary of (HHS) on how to accelerate the development and adoption of health information technology. AHIC was formed by the Secretary to help advance efforts to achieve President Bush's goal for most Americans to have access to secure electronic health records by 2014.[57]

The National eHealth Collaborative has held several board of directors meetings since its inception in November 2008, as it transitions from a federal advisory body to a public-private partnership, with significant public sector input. The status of AHIC's seven workgroups (which contained many industry and trade association experts), as well as the successor organization's priorities, is unknown. Therefore, this transition may present opportunities for greater stakeholder involvement in the transformation of Health IT and telemedicine.

In addition, industry can influence telemedicine policy by providing input on Medicare and Medicaid reimbursement schedules and fees through the legislative and Federal Register processes. Industry can also promote codification (and increased funding) for HHS's Office of the National Coordinator, and demonstrate the effectiveness and applicability of telemedicine technologies and procedures for federal government employees, Congressmen, and Capitol Hill staff.

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[55] Continua Health Alliance website: http://www.continuaalliance.org/home.

[56] Website address is http://www.nationalehealth.org.

[57] AHIC information available through the following HHS website link: www.hhs.gov/healthit/ahic.

VI.   Global Telemedicine Activities (Primarily Europe and Australia)

Telemedicine deployment is not limited to the United States. In fact, telemedicine provides unique opportunities to deliver healthcare into areas of the world where it might not be otherwise possible. While there has been considerable discussion in the United States, the European Commission and Australia have already undertaken significant initiatives within their borders demonstrating potential telemedicine applications. In addition, countries like India have expressed interest in telemedicine for healthcare delivery.

European Commission

- The EU Information and Communication Technologies (ICT) Unit for Health: Launched in 1989, the current mission is "eHealth Enabled Citizen-Centered Care." To date, over 450 projects have been supported, with funding exceeding 1 billion Euros. Initial priorities included telemedicine, homecare, electronic health records and regional health information networks; however, other areas (such as personal health systems, patient safety, and predictive medicine) now lead the ICT Unit for Health agenda.[58]

- The European Commission's Information Society and Media Directorate: In December 2007, the Directorate published "Accelerating the Development of the eHealth Market Europe."[59] The report identifies eHealth as a "lead market opportunity", defined as "a market for innovative products and services or technological solutions with high growth potential; a market where EU industry can develop competitive advantage to lead in international markets; a market that requires action by the public authorities to deal with regulatory obstacles[60]…telemedicine and homecare is the segment with the greatest potential for financial and clinical impact and is due for immediate explosion."[61]

- Infrastructure Initiatives by European Countries: Focus areas include electronic health records; increased broadband Internet and communications capability; e-prescribing; and patient summaries. Denmark, the Netherlands,

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[58] Ilias Iakovidis presentation to the World of Health IT conference, Vienna, Austria October 23, 2007; http://www.worldofhealthit.org/docs/presentations/31_iakovidis.pdf.

[59] Report available at http://ec.europa.eu/information_society/activities/health/docs/lmi-report-final-2007dec.pdf.

[60] Ibid, p. 5.

[61] Ibid, p. 14.

Germany, and the Scandinavian countries have led these efforts. The EU eHealth market is estimated at 20 billion Euros. Some Europeans believe telemedicine's technical challenges will be the least daunting hurdles; "…legal, ethical, economic, social, medical, organisational, and cultural aspects" also play important roles.[62] Language barriers may also be an impediment.

- <u>Integrating the Healthcare Enterprise (IHE-referenced above)</u> has actively advanced European Health IT efforts, but does not specifically focus on telemedicine, leaving most work to sector experts. IHE and COCIR have promoted "connect-a-thons" within the European Health IT community to increase interoperability of products and technologies. IHE has also used their global network of technical committees to identify best practices for specific medical specialties.

Australia

Australia has also been active in Health IT and telemedicine, as the National E-Health Transition Authority (NEHTA) is focusing on standards and infrastructure, along with three new initiatives: "a national clinical terminology…a national individual identifier for healthcare purposes… (and) a national healthcare provider identifier."[63] NEHTA has also been involved in developing e-Health standards and infrastructure, including shared electronic health records, common language for health communications, and clinical information specifications. In addition, Australia's University of Queensland sponsors a Center for Online Health, "…a research and teaching center…focus(ed) on (evaluating) telehealth for the delivery of health services."[64]

The European Commission and Australia are among the worldwide leaders in adopting policies affecting Health IT and telemedicine. There appears to have been little harmonization to date of international standards and regulations directly impacting these sectors. There are at least four explanations for this situation: 1) countries at varying points in developing and implementing Health IT; 2) differences in standards, regulations and privacy/security considerations in each

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[62] Information in this paragraph is available at the following website:
http://ec.europa.eu/information_society/activities/health/policy_action_plan/interoperability/index_en.htm.

[63] NEHTA Annual Report 2006-2007, October 29, 2007, p. 4; is available via website http://www.nehta.gov.au.

[64] Website for the Center for Online Health is at http://www.uq.edu.au/coh/index.html?page=18388.

country; 3) difficulty in measuring effectiveness of competing models of Health IT and telemedicine delivery and 4) (in some cases) shifting or changing priorities.

World Health Organization (WHO) and World Trade Organization (WTO)

The WHO has an e-Health for health care delivery (eHCD) program, including telemedicine concepts such as e-prescribing, tele-consultations and use of store-and-forward technologies. WHO published a strategy paper on the sector in 2004[65] and has its European offices work together with multiple stakeholders, including the World Bank, European Commission and the European Space Agency. In addition, WHO and the WTO Secretariat co-authored a 2002 report[66] showing the intersection of WTO trade agreements and health, which included a short section on telemedicine. As of 2005, WHO had created an on-line education website on e-Health for health professionals in Sri Lanka;[67] however, it does not appear that WHO has done additional work recently in the telemedicine area.

It will likely take several years until consensus is reached on the best Health IT and telemedicine delivery models. As this process proceeds, countries can engage each other on how best to globally harmonize individual country approaches within these sectors.

VII. Conclusion

Telemedicine represents a series of technologies and procedures significantly different from current healthcare practices. Using technology to break down distance barriers, remotely connecting specialists with patients needing advanced medical treatment, and allowing greater exchange of images and health data are just a few of the advantages of widespread deployment of telemedicine. Some experts think telemedicine's electronic interconnectedness will result in a better "track record" of a patient's medical decisions, reducing liability concerns. A population surge, coupled with an expected shortage of healthcare professionals, over the coming decades accentuates the need for telemedicine. However, the environment for adopting these paradigms has not changed markedly in recent years.

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[65] Report available through the WHO website at http://www.who.int/eht/en/eHealth_HCD.pdf.

[66] "WTO Agreements and Public Health;" report available at http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf; section on telemedicine begins on page 133.

[67] Home page for initiative is at http://www.who.int/ehealth/srilanka.

Consequently, the telemedicine industry needs guidance and assistance regarding domestic deployment of technologies and procedures, as well as target markets for U.S exports. In addition, U.S. firms may fall further behind in developing innovative solutions for medical conditions using telemedicine unless the pace of testing, adoption, reimbursement and implementation of these technologies increases dramatically. The time to raise telemedicine's profile has arrived, so that patients across the United States and the globe can benefit from the efficiencies that telemedicine can provide in fulfilling healthcare needs.