

**Testimony before the Committee on Small Business Subcommittee on Health and Technology**

**July 31, 2014**

Karen S. Rheuban MD  
Professor of Pediatrics  
Director, University of Virginia Center for Telehealth  
P.O. Box 800711  
University of Virginia Health System  
Charlottesville, Virginia, USA 22908  
[Krheuban@virginia.edu](mailto:Krheuban@virginia.edu)  
434-924-2481 (phone)  
434-982-1415 (fax)

Chairman Collins, Ranking Member Hahn, members of the Subcommittee on Health and Technology, thank you for the invitation to provide testimony regarding the opportunities and challenges for small medical practices seeking to incorporate telehealth into everyday practice. My name is Dr. Karen Rheuban, and I direct the Center for Telehealth at the University of Virginia. I am the Principal Investigator of the federally funded Mid Atlantic Telehealth Resource Center, a past president of the American Telemedicine Association and Board Chair of the Virginia Telehealth Network. I also have the privilege of serving as Board Chair of the Virginia Department of Medical Assistance Services (Medicaid). Although the focus of my testimony relates to opportunities for and barriers to the use of telehealth at the provider level, it is also important to note there are parallel implications for small business development in sectors such as telemedicine services companies and technology innovation.

“Telemedicine” is defined as the practice of medicine using electronic communications, information technology or other means between a provider in one location, and a patient in another location. Generally, telemedicine is not an audio-only telephone conversation, e-mail/instant messaging conversation, or fax. Telemedicine is

not a new specialty, a new procedure or a new clinical service but rather, technology designed to enable the provision of healthcare services at a distance. 21<sup>st</sup> Century telemedicine services can be provided live, via high definition interactive videoconferencing supported by peripheral devices, or provided asynchronously, using store and forward technologies, or through the use of remote patient monitoring tools.

Telemedicine has been demonstrated to mitigate many of our nation's significant challenges including disparities in access to care, healthcare workforce shortages, and geographic mal-distribution of providers. Telemedicine improves patient triage, clinical outcomes, reduces the burden of travel for care, and fosters more timely access to care. Telemedicine tools support patient engagement and self-management where appropriate, and, as supported by extensive evidence published in the peer-reviewed literature, improves clinical outcomes, and lowers the cost of care.<sup>1, 2</sup>

Vetted by and in collaboration with the relevant specialty societies, the American Telemedicine Association has developed and published practice guidelines designed to ensure best practices in telemedicine that ensure high quality care.

Examples of telehealth supported care include:

- Remote diagnosis of stroke with timely use of thrombolytic (clot busting) agents to reduce morbidity and mortality, improve patient outcomes, and lower overall costs of care;

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<sup>1</sup> Lustig, Tracy A. The role of telehealth in an evolving health care environment: workshop summary. National Academies Press, 2012.

<sup>2</sup> Schwamm, Lee H., Heinrich J. Audebert, Pierre Amarenco, Neale R. Chumbler, Michael R. Frankel, Mary G. George, Philip B. Gorelick et al. "Recommendations for the Implementation of Telemedicine Within Stroke Systems of Care A Policy Statement From the American Heart Association." *Stroke* 40, no. 7 (2009): 2635-2660.

- Delivery of telemedicine supported obstetrical services to women at high risk for complicated pregnancies ultimately resulting in improved clinical outcomes, lessened infant mortality rates, reduced days in neonatal intensive care and lower costs of care;
- Regular ophthalmologic screening of patients with diabetes for retinopathy, the number one cause of blindness in working adults;
- Better management of chronic illness such as heart failure, diabetes, hypertension, chronic obstructive pulmonary disease;
- Improved access to cancer screening tools, collaborative diagnosis through virtual tumor boards and even remote access to clinical trials;
- Access to mental health services for children and adults to include emergency psychiatry services;

Telemedicine supports an integrated systems approach focused on disease prevention, enhanced wellness, chronic disease management, decision support, improved efficiency, quality and patient safety.<sup>3</sup>

Opportunities for small practices to adopt telehealth relate to the model they wish to deploy and the credentials of the provider. Primary care providers can serve as “originating sites” so as to connect their patients to specialists, they may offer direct-to-consumer services for their own patients, they may choose to serve on panels for telemedicine services companies offering direct-to-consumer services for their own patients or others, and/or they may engage in remote patient monitoring services for chronic disease management for their patients. Specialty care providers may serve as

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<sup>3</sup> Kvedar, Joseph, Molly Joel Coye, and Wendy Everett. "Connected health: A review of technologies and strategies to improve patient care with telemedicine and telehealth." *Health Affairs* 33, no. 2 (2014): 194-199.

consulting “distant site” providers to provide consultative services and follow up visits either through their offices or at the hospital. Specialists may also serve as “originating sites” to connect to other providers. They may offer services live using videoconferencing technologies or through store and forward applications. Specialty care providers may choose to serve on panels of consultants for telemedicine services companies, offer direct-to-consumer services for their patients or for payers and telemedicine services companies, and participate in remote patient monitoring models. Regardless of the model chosen, it is imperative that willing providers take into consideration all relevant federal, state, specialty society policies and best practices that impact telehealth practice.

**A) *Rural healthcare:***

Although rural communities face the same basic challenges in access, quality and cost as their urban counterparts, they do so at far greater rates, attributable to a host of factors. “Core health care services” as defined by the Institute of Medicine as primary care, emergency medical services, long term care, mental health and substance abuse services, oral health and other services are considerably less accessible in rural communities.<sup>4</sup> Where local specialty care services are not available, particularly in rural and underserved regions and health professional shortage areas, telemedicine offers timely access to care and spares patients the burden of long distance travel for access to that care.

Rural communities lack sufficient patient volumes to support specialty and subspecialty practices. Primary care providers are often overwhelmed with complex

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<sup>4</sup> Institute of Medicine, Committee on the Future of Rural Health Care. "Quality through collaboration: The future of rural health care." (2004).

patients with acute and chronic illness. Telehealth technologies offer ready access to critical services when rural providers partner with tertiary and quaternary care facilities.

Attracting health professionals to rural communities remains a daunting task and retaining those health professionals to practice in rural communities is all the more difficult. Rural healthcare providers generally work longer hours, see more patients and have greater on-call demands because of lack of cross coverage opportunities. Strategies to recruit and retain clinicians to practice in rural and frontier communities must include applications that enhance the management of patients with acute and chronic illness, and reduce the chronic sense of isolation experienced by those practitioners by affording enhanced connectivity to colleagues, and educational opportunities.

Telehealth should be viewed as integral to rural development. More than 90% of patients seen through our UVA telemedicine program remain within their community healthcare environment, resulting in a reduction of unnecessary transfers, and thereby contributes to the economic viability of community hospitals.

**B) *Urban healthcare***

Although the challenges of unfavorable geography and distance tend to be uniquely rural, socioeconomic issues, health disparities, and other serious barriers to access to quality healthcare are equally compelling in urban areas. Poverty, unhealthy behaviors and adverse health status indicators are as prevalent in the shadow of our finest urban academic health centers as they are in rural communities. Isolated, vulnerable urban patients also suffer from high rates of chronic illness, and for whom a bus ride across town can be as challenging as is a long ride for a rural patient.

**C) *Workforce***

It is widely accepted that our nation faces a shortage of physicians and other health professionals which is anticipated to worsen with our aging population, higher rates of chronic illness, and greater numbers of covered individuals seeking care following the implementation of the Affordable Care Act. The Association of American Medical Colleges (AAMC) in a recent communication with the Committee on Veterans Affairs reported an estimated shortage of 46,000 primary care physicians and 45,000 specialists by 2020.<sup>5</sup> The incorporation of telehealth technologies into integrated systems of care offers tools with great potential to address some of the challenges of access, specialty shortages, and changing patient needs both in the rural and urban setting.

The aging of our population has already created increased demand for specialty healthcare services to address both acute and chronic disease in the elderly. Such a demand, in the face of anticipated provider shortages, requires a fundamental shift from the model of physician centered care to one focused on patient centered care using interdisciplinary teams, evidence based medicine, the use of informatics in decision support and telehealth technologies when specialty care services are not locally available. Home telehealth and remote monitoring in the arena of chronic disease management improves care and prevents hospital readmissions.

To facilitate this paradigm shift, it is imperative that we train a broad spectrum of health professionals to deliver 21<sup>st</sup> Century healthcare facilitated by telehealth technologies.

**D) Example: The University of Virginia Center for Telehealth**

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<sup>5</sup><https://www.aamc.org/download/385178/data/aamlettertocongressionalconfereesonveteranaffairslegislation.pdf>

The UVA Telemedicine program serves as an example of both traditional and innovative applications in telehealth. Our Center for Telehealth was established initially as the Office of Telemedicine in 1996. Since the establishment of our program, we have developed collaborations and agreements connecting the UVA Health System with 128 sites across the Commonwealth using high definition video-teleconferencing, store and forward technologies, remote patient monitoring and mobile health applications to improve access to healthcare services for the citizens of the Commonwealth. We connect with hospitals, clinics, health centers, community service boards, medical practices, correctional facilities, skilled nursing facilities and emergency medical services. Our telemedicine program has reduced the burden of travel for Virginians by more than 9 million miles, saved lives and fostered innovative models of care delivery and workforce development. We have launched a care coordination and remote patient monitoring program designed to reduce hospital readmissions, and to manage chronic disease in the community setting. UVA telemedicine supported clinical care spans the continuum from prenatal services, to acute care consultations and follow up visits, to chronic disease management and palliative care. We have leveraged these efforts to also expand broadband communications services in rural regions of the Commonwealth.

The UVA Telemedicine program has received funding from HRSA, USDA, the Department of Commerce, and the Rural Healthcare Support Mechanism of the Federal Communications Commission. We have worked with our colleagues at the Centers for Medicare and Medicaid Services, and with the Institute of Medicine to help advance the implementation of policies that allow for innovation, sustainability and high quality patient care. In 2010, the Center was awarded a federal grant to serve as the Mid

Atlantic Telehealth Resource Center (MATRC) to provide technical assistance to providers, healthcare systems, state governments and other entities in eight states and the District of Columbia.

The Center for Telehealth has also worked closely with all relevant agencies of the Commonwealth of Virginia to help build our telemedicine network , to pilot innovative applications, and to ensure sustainability through sound state public policy collaborations that integrate telehealth into mainstream healthcare in the Commonwealth. These efforts led to broad reimbursement by Virginia Medicaid in 2003 and in 2010, a legislative mandate for parity third party payment.

Our Center for Telehealth tracks a host of metrics to include process metrics for emergency care (time from consult request to completion of encounter), process metrics for non-emergency services which are compared to traditional face to face services, clinical outcomes metrics, hospital readmissions rate, miles of travel avoided, comparisons to national benchmarked telemedicine programs, patient satisfaction, and other organizational metrics.

Examples of UVA telemedicine clinical outcomes metrics include:

- a) High-risk obstetrics telemedicine in which we compared traditional face to face care with care provided via telemedicine to 374 high risk pregnant women. We have documented a reduction in NICU hospital days for the infants born to these patients by 39% compared to control patients, reduced patient no-shows by 62% and reduced patient travel by these pregnant women by 162,000 miles.<sup>6</sup>

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<sup>6</sup> Veith, Sharon T et al, "Perinatologists and Advanced Practice Nurses Collaborate to Provide High Risk Prenatal Care in Rural Virginia Communities." In *Association of Women's Health, Obstetric and Neonatal Nurses (June 14-18, 2014)*. AWHONN, 2014.

- b) In partnership with BroadAxe Care Coordination, remote patient monitoring tools have been deployed to prevent hospital readmissions and have been an effective tool for patients with heart failure, acute myocardial infarction, chronic obstructive pulmonary disease, and pneumonia, reducing all cause 30 day readmissions by 45%.
- c) Store and forward ophthalmologic screening for retinopathy, the number one cause of blindness in working adults has been provided to underserved adults with diabetes. Over two years, 1736 screens have been performed, with 802 abnormal patients identified (46%) as being at risk for blindness.
- d) Remote patient monitoring tools have been used to reduce the burden of diabetes in the community setting. All clinical metrics tracked (Hgb A1c, fasting blood sugar and blood pressure) have had impressive reductions in the range of 9-10%.
- e) More than 2000 patients have participated in the video-based interactive patient education programs of our diabetes community network.

**E) Issues for consideration:**

Despite the federal government and private industry's multi-billion dollar investment in telemedicine, broadband expansion and health information technologies, disappointingly, efforts to promulgate continued integration of telemedicine remain stifled by 20<sup>th</sup> Century federal and state barriers to more widespread adoption. If challenging to large healthcare systems such as ours, it follows naturally that despite great promise, these obstacles create significant challenges for small medical practices seeking to use telehealth tools. Larger systems can draw upon the expertise of contract attorneys, information technology specialists, a robust billing staff, electronic medical

records and picture archiving and communications services, credentialing and privileging staff, and other support systems to help facilitate telehealth integration.

Currently, 26 different federal agencies report engagement in telehealth, be it through research or other grant funding opportunities, the establishment of broadband communications networks, clinical service delivery, device development and regulation, and other interests. The Fed-Tel working group efforts to coordinate telehealth policy has made some progress, however, there still remains a serious lack of coordination of practical policies across these agencies in part because of statutory barriers.<sup>7</sup>

As an example: mal-aligned federal definitions of rural have resulted in federal grant support for telemedicine technology and broadband connectivity deployed to certain clinics and hospitals eligible for funding according to those agency definitions of rural, but sustainability is thwarted by statutory barriers that deny Medicare reimbursement because of a more limited Medicare definition of rural and other originating site restrictions. Inconsistent state policies and regulations create additional barriers for otherwise willing providers seeking to integrate telehealth into care delivery models.

### **1) Reimbursement**

#### **a) Medicare:**

Payment coverage restrictions remain a major impediment to the broader adoption of telehealth by providers. Congress, in 1997, through the Balanced Budget Amendment, and in 2000, though the Benefits Improvement and Protection Act (BIPA),

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<sup>7</sup> Doarn, Charles R., Sherilyn Pruitt, Jessica Jacobs, Yael Harris, David M. Bott, William Riley, Christopher Lamer, and Anthony L. Oliver. "Federal Efforts to Define and Advance Telehealth—A Work in Progress." *Telemedicine and e-Health* 20, no. 5 (2014): 409-418.

authorized the Center for Medicare and Medicaid Services (CMS) to reimburse for telehealth services provided to rural Medicare beneficiaries across a broad range of CPT codes and services. However, the current Medicare telehealth provisions in the Social Security Act 1834(m), enacted in 2000, have not kept pace with advancements in technology, and more than a decade of best practices and outcomes research. In the Act, Congress, directed CMS to study and report opportunities to expand coverage within two years. Fourteen years later, no such report has been produced.<sup>8</sup>

The Affordable Care Act did not expand eligible originating sites in the traditional Medicare program in part because of adverse scoring by the Congressional Budget Office that failed to take into account services provided in lieu of face to face care, and Medicare savings accrued by patient monitoring programs. Pilot programs have been launched through the Center for Medicare and Medicaid Innovation that include remote patient monitoring. The regulations for Accountable Care Organizations still require the patient originating site to conform to the regulations set forth in Section 1834 (m) without flexibility to include providers serving patients living in metropolitan communities across the nation including patients in nursing homes.<sup>9</sup> These statutory barriers placed on telehealth programs are borne out by the meager reimbursements reported by CMS for telemedicine services. **In 2013, CMS reported fewer than \$12 million dollars in reimbursements for “allowable charges” NATIONWIDE which include distant site and originating site fees.** (Attachment A: CTEL). Although physician offices and community based clinics are ideal originating sites for telemedicine

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<sup>8</sup> Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) section 223(d)

<sup>9</sup> Grabowski, David C., and A. James O’Malley. "Use of telemedicine can reduce hospitalizations of nursing home residents and generate savings for medicare." *Health Affairs* 33, no. 2 (2014): 244-250.

encounters, the current Medicare originating site payment (\$24.63) is insufficient to cover the costs of establishing and maintaining a telemedicine service. In its 2014 physician payment schedule, CMS expanded its operating definition of rural from non-metro counties only to also include those regions defined as rural by the Office of Rural Health Policy.

**b) Medicaid:**

Currently 47 state Medicaid programs provide **some** form of reimbursement for the delivery of telehealth facilitated care to Medicaid beneficiaries. However, there is no consistency in telehealth coverage across the Medicaid programs, despite clear needs of patients served by our Medicaid programs and in the face of coverage expansion post implementation of the Affordable Care Act . Most Medicaid programs pay for transportation of patients and yet, in many states, there are still considerable limitations on coverage for telehealth services. In 2013, Virginia Medicaid expended \$70 million dollars on non-emergency transport of Medicaid beneficiaries.<sup>10</sup> A consistent federal-state approach to Medicaid payment for telehealth services would provide cost-savings both in operations costs (transportation) and more importantly, in access to care and models of care delivery. Virginia Medicaid has taken many positive steps integrating telehealth for its beneficiaries, and since 2003, has provided telehealth coverage for urban and rural beneficiaries. Virginia Medicaid covers live-interactive video based consultations and follow-up care for all Medicaid enrollees. Our Medicaid program has begun to cover certain store-forward services by Medicaid providers, and has integrated remote patient monitoring for our (urban and rural) dual enrollees, the most vulnerable and costly patients we serve, though our newly launched pilot with CMS

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<sup>10</sup> Communication with Hazelton, A., Virginia Department of Medical Assistance Services, July 2014

“Commonwealth Coordinated Care”. Virginia Medicaid has also expanded the list of eligible providers and services beyond the eligible providers in Medicare. Medicaid coverage decisions requested by providers are analyzed based on clinical need, technical viability of the service, models supported by other payers, support of professional organizations, establishment of protocols, costs, and risk of fraud and abuse. In 2013, Virginia Medicaid reported reimbursements of \$570,000 for more than 10,000 telemedicine claims in the fee for service and managed care programs.<sup>11</sup>

**c) Private pay:**

Twenty-one states plus the District of Columbia require that private insurance cover telehealth services. These states are: Arizona, California, Colorado, Georgia, Hawaii, Kentucky, Louisiana, Maine, Maryland, Michigan, Mississippi, Missouri, Montana, New Hampshire, New Mexico, Oklahoma, Oregon, Tennessee, Texas, Vermont, Virginia, and the District of Columbia. Some of the commercial payers support payment for telemedicine services even in the absence of a state mandate. Others have developed or adopted direct-to-consumer models as either a benefit to members, or an additional payment option.

**d) Other models:**

A number of telemedicine services companies have developed models to provide contractual services to hospitals, correctional facilities and other entities, by recruiting individual physician providers and contractually fully managing the interface between physician, hospital and patient (examples: *Specialists on Call®*, *Insight Telepsychiatry®*). Other companies contract with payers or directly with patients in the

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<sup>11</sup> Communication: Nelson, J, Virginia Department of Medical Assistance Services, July 2014

direct to consumer model (examples: *Teladoc®*, *American Well®*, *MD Live®*) and offer services via video-based encounters and telephone services to the home, workplace or travel locations. The Federation of State Medical Boards<sup>12</sup> and the American Medical Association<sup>13</sup> have issued recent policy documents and guiding principles to ensure patient safety, quality of care, privacy of patient information, protecting the patient-physician relationship while promoting improved care coordination and communication with medical homes.

## **2. Boards of Medicine policies:**

Inconsistent board regulations across the states and territories have led to continued confusion for practitioners. Some state boards have adopted positions of opposition to the mainstream adoption of telehealth requiring an in-person visit prior to any subsequent telehealth encounters. We **applaud** the Federation of State Medical Boards, for its April, 2014 Report *Appropriate Regulation of Telemedicine (SMART) Workgroup report*. This report, “*Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*” establishes a framework and common language for adoption by the states.<sup>12</sup> As stated by the FSMB, “this new policy document provides guidance to state medical boards for regulating the use of telemedicine technologies in the practice of medicine and educates licensees as to the appropriate standards of care in the delivery of medical services directly to patients via telemedicine technologies. It is the intent of the SMART Workgroup to offer a model policy for use by state medical boards in order to remove regulatory barriers to widespread appropriate

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<sup>12</sup> [http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB\\_Telemedicine\\_Policy.pdf](http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf)

<sup>13</sup> REPORT 7 OF THE COUNCIL ON MEDICAL SERVICE (A-14) Coverage of and Payment for Telemedicine, June, 2014

adoption of telemedicine technologies for delivering care while ensuring the public health and safety.” Notably, this working group provided guidance to the Boards of Medicine that an initial telemedicine encounter (live interactive video based or store and forward) can indeed establish a bona-fide doctor patient relationship so long as the encounter conforms to current standards of practice. Indeed, our experience and that of others supports that concept. Timely access to care is a key driver of telemedicine programs ....as an example, it is highly unlikely that any acute stroke victim might pre-emptively have scheduled an in person visit with a stroke neurologist prior to suffering his/her first stroke. We rely upon our clinicians and their respective specialty societies to determine the wisdom and need for an initial in-person visit when developing our telehealth protocols.

The SMART Working group also established additional guidelines for the Boards that address informed consent, privacy and security of patient records, patient choice, prescribing, licensure, continuity of care and access to emergency care. In particular, the FSMB model policy clearly states that prescribing as a result of a telemedicine encounter should follow all current standards of practice in terms of indications, appropriateness and safety considerations.

### **3. Credentialing and Privileging**

Credentialing and privileging are important elements of telehealth practice so as to ensure patient safety, quality and that appropriate services are provided by the appropriately credentialed provider. Telehealth has been incorporated into the Joint Commission standards beginning in 2000 and in their revised standards of 2004. In 2011, after extensive deliberations with telehealth providers, CMS published much

welcomed new regulations in its hospital Conditions of Participation standards to address credentialing and privileging to include proxy arrangements so as to further facilitate the delivery of telemedicine services across the nation.<sup>14</sup> Despite this progress, there remain delays in the credentialing and privileging processes, and confusion amongst practitioners and hospitals regarding roles and responsibilities to include the requisite sharing of quality data.

#### **4. Licensure**

State medical licensure is a slow, costly and cumbersome process for providers who wish to offer services through telemedicine to patients physically located in other states. The process of securing multiple licenses is time consuming at its best, with requirements for extensive primary source verification, an application and fee for licensure in the states in which the provider might wish to evaluate and treat patients. So as to ensure the ability of the Boards to respond to complaints and enforce actions against providers, in response to requests for licensure portability, in April, 2014, the Federation of State Medical Boards (FSMB) developed an expedited licensure process. As compared to true licensure portability, as has been applied in the Nurse Compacts and as proposed in legislative proposals, this new process still risks being time consuming and costly to providers. Nonetheless, the FSMB expedited licensure proposal is an improvement over current licensure policy.

#### **5. Stark and Anti-kickback laws**

Providers and healthcare systems must be aware of the implications of the Stark and Anti-kickback laws when considering models for acquisition of telehealth equipment and technology. As reported on the CMS website, “the Anti-Kickback Statute (42 U.S.C.

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<sup>14</sup> [http://www.ofr.gov/OFRUpload/OFRData/2011-10875\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2011-10875_PI.pdf).

Section 1320a-7b(b) makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program.<sup>15</sup> Where remuneration is paid, received, offered, or solicited purposefully to induce or reward referrals of items or services payable by a Federal health care program, the Anti-Kickback Statute is violated.

The Physician Self-Referral Law (Stark Law) (42 U.S.C. Section 1395nn) prohibits a physician from making a referral for certain designated health services to an entity in which the physician (or an immediate member of his or her family) has an ownership/investment interest or with which he or she has a compensation arrangement, unless an exception applies.”

Both these statutes must be considered as important risks for telemedicine providers or entities who “purchase, lease, order, or arrange for or recommend the purchasing, leasing, or ordering of any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program.....Health care providers must take utmost precaution and care in developing processes and procedures to implement telemedicine programs to avoid liability under the Stark and Anti-Kickback statutes”.<sup>16</sup>

## **6. Broadband availability:**

The Rural Healthcare Program of the Federal Communications Commission’s Universal Service Fund was established following the passage of the Telecommunications Act of 1996. This program has been extraordinarily useful in expanding broadband services for eligible entities located in rural areas by providing

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<sup>15</sup> [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud\\_and\\_Abuse.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf)

<sup>16</sup> Ali, S. <http://ctel.org/wp-content/uploads/2011/12/CTeL-The-Practice-of-Telemedicine-The-Impact-of-Stark-and-Anti-Kickback.pdf>

discounts for ongoing connectivity that compare to those rates available to urban providers. Unfortunately as compared to the e-Rate, High Cost, and Low Income programs, the Rural Healthcare Programs have not fully met their Commission defined funding cap because of onerous, complex application processes, and statutory exclusions to eligibility that do not always align with health disparities. In the Telecommunications Program, as an example, for profit hospitals, initially considered ineligible entities, may receive funding support for connectivity to the Emergency Department but other connections within that hospital are not eligible, even if that hospital is the sole provider in a rural county.<sup>17</sup>

Other ineligible entities include emergency medical services providers and skilled nursing facilities. For-profit clinics and solo practices are not eligible for support. Good faith efforts by the FCC to expand within their statutory authority, has led to somewhat broader use of the Telecommunications Program. The FCC Pilot Program and the Health Care Connect Fund, allows, through consortia, collaborations that may include urban providers. Chapter 10, *Healthcare*, of the National Broadband Plan, outlined important steps to integrate broadband communications services into sustainable models of healthcare delivery.<sup>18</sup>

Despite significant outreach efforts, through 2012, utilization of the fund still remains less than 30% of the funding cap established by the Commission after passage of the Telecommunications Act of 1996. Total funding commitments reported on the Rural

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<sup>17</sup> *FCC Report and Order, Order on Reconsideration and further Notice of Proposed Rule Making*, Federal Register: January 22, 2004 Volume 69, Number 14

<sup>18</sup> Thomes, Cynthia. "The National Broadband Plan: Connecting America. Administered by the Federal Communications Commission, 445 12th Street SW, Washington, DC 20554. Retrieved October 15, 2010, from <http://www.broadband.gov>." (2011): 435-436.

Healthcare website through June 2012 were \$114,123,355 of which \$47,723,468.67 were allocated to providers in Alaska.<sup>19</sup>

The cumbersome and time consuming application process and confusing regulations surrounding the rural healthcare programs remain a disincentive for participation by individual providers and small practices even if they otherwise meet the eligibility requirements set forth in the Act.

## **7. Patient Privacy and Disclosure**

Providers must ensure that any telemedicine collaboration conform fully to the regulations of the Health Insurance Portability and Accountability Act (HIPAA). As with in-person healthcare, providers have a duty to maintain confidentiality and security of patient data. Where a technical staff is included in the healthcare team at both originating and distant sites, and with the additional components of technologies and communications service providers, it is imperative that providers pay special attention and adhere to both the privacy and security elements of the HIPAA regulations. The HIPAA Omnibus Rule requires that providers and their healthcare associates have in place a Business Associate Agreement (BAA) when interactions include protected health information. Business associates include entities that create, receive, maintain, or transmit protected health information to perform certain functions on behalf of a covered entity. They also include subcontractors of the business associate delegated a function, activity, or service in a capacity other than as a member of the business associate's workforce. HIPAA also requires the covered entity be able to conduct audit trails to ascertain the presence of breaches which is not readily available with certain video based applications. As an example, in 2011, Skype issued the following statement:

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<sup>19</sup> <http://www.usac.org/rhc/tools/news/default.aspx?pgm=telecom>

*“Skype is not a business associate subject to HIPAA, nor have we entered into any contractual arrangements with covered entities to create HIPAA-compliant privacy and security obligations. Instead, Skype is merely a conduit for transporting information, much like the electronic equivalent of the US Postal Service or a private courier. Skype does not use or access the protected health information (PHI) transmitted using our software. However, Skype has implemented a variety of physical, technical and administrative safeguards (including encryption techniques) aimed at protecting the confidentiality and security of the PHI that may be transmitted using Skype’s calling and video calling products.”<sup>20</sup>*

Many practitioners are unaware of the complex nuances of these regulations as they relate to telemedicine and do not have in place the legal infrastructure to assist them in managing the additional regulations that govern telehealth practice.<sup>21</sup>

## **8. Informed consent**

Informed consent is a requisite element of all healthcare encounters. Telehealth practice adds additional layers of disclosure, to include authentication of the identity and location of the patient and provider, provider credentials, and delivery systems utilized during the encounter. In addition, providers must have in place an emergency plan should the clinical situation warrant a higher level of care, and a plan for care in the event of technology failure and all should be disclosed to the patient as a component of the consent.

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<sup>20</sup> Skype Statement: [onlinetherapyinstitute.com/2011/03/videoconferencing-secure-encrypted-hipaa-compliant/](http://onlinetherapyinstitute.com/2011/03/videoconferencing-secure-encrypted-hipaa-compliant/)

<sup>21</sup> <http://caltrc.org/wp-content/uploads/2014/01/HIPAA-for-TRCs-2014.pdf>

The FSMB Model Policy makes the following recommendations regarding Informed Consent.<sup>12</sup>

“Appropriate informed consent should, as a baseline, include the following terms:

- Identification of the patient, the physician and the physician’s credentials;
- Types of transmissions permitted using telemedicine technologies (e.g. prescription refills, appointment scheduling, patient education, etc.);
- The patient agrees that the physician determines whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter;
- Details on security measures taken with the use of telemedicine technologies, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy notwithstanding such measures;
- Hold harmless clause for information lost due to technical failures; and
- Requirement for express patient consent to forward patient-identifiable information to a third party.”

## **9. Standards and Practice Guidelines:**

The American Telemedicine Association and its >2500 member supported Special Interest Groups, Committees and Discussion groups have developed standards to address technical applications, and clinical practice guidelines, many of which have been endorsed by specialty societies.<sup>22</sup>

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<sup>12</sup> FSMB

<sup>22</sup> Krupinski, Elizabeth A., and Jordana Bernard. "Standards and Guidelines in Telemedicine and Telehealth." In *Healthcare*, vol. 2, no. 1, pp. 74-93. Multidisciplinary Digital Publishing Institute, 2014.

These standards and practice guidelines extend beyond the practice guidelines that currently exist for traditional healthcare. The development of standards and guidelines, addressing both interoperability (such as HL7, DICOM, or H.320, 323, 324, compression standards for videoconferencing) and specialty specific applications (such as teleophthalmology or telepathology), will increase functionality related to and acceptance of advanced technologies applied to healthcare. The Special Interest Groups of the American Telemedicine Association have worked collaboratively with the clinical specialty societies to develop practice guidelines in telehealth that conform to accepted standards of care. These guidelines are developed after careful review of the evidence, and in consultation with the specialty societies. Examples include teleophthalmology, teledermatology, telemental health, tele-ICU, home telehealth, telerehabilitation, and telepathology. Practice guidelines and standards guide providers and payers in models of best practice, informed by the evidence.

## **10. Provider education, technical support and training**

Training programs in telehealth are important additional elements of health professional education and include the appropriate use of telehealth technologies, board regulations, relevant standards and guidelines, interprofessional models of practice enhanced by telehealth, and specific training to operate and troubleshoot videoteleconferencing equipment, devices and patient monitoring tools. The American Telemedicine Association offers certification for certain for-credit programs, and others have developed hybrid on-line and hands on training. With HRSA funding, and in partnership with the Virginia Health Workforce Development Authority we have trained 300 health professionals across the disciplines to become certified telehealth presenters,

and/or coordinators to keep pace with the demand for such trainees. Telehealth should be incorporated into every medical and nursing school curriculum, with subsequent experiences during graduate medical education so as to prepare our physicians and nurses on the appropriate use of telehealth in everyday practice.

### ***11. The evidence:***

In 2013, the American Telemedicine Association reported “Over 40 years of research has yielded a wealth of data about the cost effectiveness and efficacy of many telemedicine applications.”<sup>23</sup>

More than 20,000 citations in the peer reviewed literature address outcomes across the specialties, including pediatric cardiology, high risk pregnancies, congestive heart failure, asthma, chronic obstructive pulmonary disease, cancer, telepathology, teleradiology, diabetes care, dermatology and wound care, to name just a few. The overwhelming evidence is that telemedicine and remote patient monitoring compares favorably with in person care, and in many cases, is associated with better outcomes.

#### ***a. Home telehealth***

Home telehealth is defined as the use of synchronous or asynchronous telecommunications technologies by a home care provider to link patients to out-of-home sources of medical care, education, or other services. These services may incorporate interactive home telehealth technologies using POTS (plain old telephone service) or broadband telecommunications technologies. Home telehealth programs generally include monitoring devices such as pulse oximetry, blood pressure, EKG, blood sugar, weight, temperature, and passive monitoring of motion. It has been reported by the Food

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<sup>23</sup> <http://www.americantelemed.org/docs/default-source/policy/examples-of-research-outcomes---telemedicine's-impact-on-healthcare-cost-and-quality.pdf>

and Drug Administration, which regulates medical devices, that home care systems represent the fastest growing segment of the medical device industry.

Home telehealth can be utilized by traditional home health agencies, for the delivery of hospice care, or for case management by providers, clinics or hospitals to facilitate chronic disease management for patients. Home telehealth programs reduce readmission rates, visits to the emergency room, physician visits, and impart significant cost savings. The federal government supports major initiatives for aging in place such as PACE, but does not cover the technologies that will keep people healthy, and independent in their own homes.

The Veteran's Administration has published data to demonstrate that the VA Care Coordination and Home Telehealth program reduces hospital admissions by 19% and hospital days by 25% for patients with chronic disease.<sup>24</sup>

Integration of home telehealth into rural models of healthcare is a particularly efficient cost-effective choice when one considers the distances traveled by home health staff in rural areas. Factoring in the time spent traveling to the home, significant cost savings accrues with the use of these technologies. Dimmock et al report the cost savings associated with the supplementation of regular in home visits by home telehealth visits at approximately \$50/visit.<sup>25</sup>

A recent analysis of the evidence for telemedicine interventions to include remote patient monitoring has identified significant cost-savings and improved outcomes when

<sup>24</sup> Darkins, Adam, Patricia Ryan, Rita Kobb, Linda Foster, Ellen Edmonson, Bonnie Wakefield, and Anne E. Lancaster. "Care coordination/home telehealth: the systematic implementation of health informatics, home telehealth, and disease management to support the care of veteran patients with chronic conditions." *Telemedicine and e-Health* 14, no. 10 (2008): 1118-1126.

<sup>25</sup> Dimmock, S et al, A case study of benefits and potential savings in rural home telemedicine, *Home Healthcare Nurse*, 2000;18 (2) 124-135.

applied to the management of chronic illness.<sup>26</sup> These findings are consistent with our earlier referenced UVA Center for Telehealth experience.

## ***12. Acceptance of advanced technologies***

Patient acceptance of and satisfaction with the use of telehealth technologies for consultation and ongoing acute and chronic care has been remarkably positive, attributable in part to the obvious benefit of timely access to locally unavailable specialty healthcare that spares patients the burden and expense of travel to remote tertiary and quaternary healthcare facilities. Indeed, we have collected data in many of our programs that demonstrates the telehealth “no-show” rate is considerably lower than the in-person clinic “no show” rate.<sup>6</sup>

Provider acceptance of advanced technologies and telehealth tools has been equally gratifying for patient consultation, patient education, distance learning opportunities, and for collaborations in remote patient monitoring.

### **Conclusion:**

Telehealth is an essential tool to address the significant challenges of access to high quality care for both acute and chronic disease management, to mitigate workforce shortages, improve population health and lower cost of care. There are many opportunities for small practices to integrate telehealth models into every-day practice. However, even for large healthcare systems, managing and navigating the complex legal and regulatory environment which impacts the practice of healthcare using telehealth tools can be challenging. For small group practices and solo practitioners, telehealth

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<sup>6</sup> Veith, Sharon T et al

<sup>26</sup> Bashshur, Rashid L., et al. "The Empirical Foundations of Telemedicine Interventions for Chronic Disease Management." *Telemedicine and e-Health*(2014).

holds great promise, but the administrative and regulatory challenges can be overwhelming. Thus it is imperative that we create and promulgate policies that foster certainty, transparency, high quality, secure and sustainable solutions that empower patients, providers and payers to adopt 21<sup>st</sup> Century models of care.

**Appendix A**



**Medicare Reimbursement for Telehealth Services through  
The Centers for Medicare & Medicaid Services**

Calendar Years 2001-2013

Medicare Telehealth Services				
	Distant Site		Originating Site	
Year	Allowed Services	Allowed Charges	Allowed Services	Allowed Charges
2001	1,494	\$ 55,422	294	\$ 5,880
2002	5,285	\$ 185,086	1,596	\$ 31,836
2003	6,776	\$ 404,764	4,389	\$ 90,186
2004	11,266	\$ 765,179	7,841	\$ 161,880
2005	15,970	\$ 1,176,329	10,972	\$ 227,349
2006	25,461	\$ 2,124,881	15,908	\$ 333,138
2007	25,395	\$ 1,991,753	14,336	\$ 310,296
2008	23,144	\$ 1,613,408	9,247	\$ 208,964
2009	37,503	\$ 2,797,893	17,100	\$ 393,291
2010	46,655	\$ 3,397,285	23,660	\$ 550,171
2011	82,701	\$ 5,938,090	32,450	\$ 761,230
2012	106,023	\$ 7,467,157	38,540	\$ 903,233
2013	136,429	\$ 10,689,862	46,147	\$ 1,112,446

Please note that the "allowed charges" represent the amount paid by both Medicare and the beneficiary (including beneficiary deductible and co-insurance).

**Here are some additional things to consider when looking at the numbers above:**

- This data only reflects services paid under the Medicare Telehealth benefit, which only includes services otherwise furnished in-person and would not include professional interpretations of diagnostic tests, for example, that are not subject to Medicare telehealth rules. These services are often referred to as "Telehealth," but are not included in this data.
- The distant site bills for the specific service furnished by reporting the same CPT or HCPCS code(s) reported when the service is furnished in-person. The originating site, by statute, can only bill for the originating site facility fee, which is a national flat fee that is updated annually. The originating site will report only one originating site facility fee, per encounter, even if the distant site practitioner furnishes more than one reportable telehealth service during the same encounter.
- The data relies on the distant site practitioner correctly applying the telehealth modifiers to claims.

**Information Provided by CMS—April, 2014**