Telehealth Promises for an Evolving Health Care Environment

*Women in Government*

*Seventh Annual Health Care Summit*

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An Introduction to Telehealth
Telehealth and the U.S. Health Care Landscape

- The U.S. health care landscape is transitioning from fee-for-service to pay-for-performance (e.g., outcomes, quality) models of care delivery
- Increased use of integrated delivery models (e.g., Accountable Care Organizations), bundled payments, medical homes, and readmissions reduction initiatives
- Growing consumer demand for in-home care modalities
- Telehealth viewed as an efficient and cost-effective care delivery vehicle
- Availability, accessibility, and ubiquity of telehealth technologies
Telehealth Drivers

- **Increasing Aging (65+) Population**
  - Projected increase in U.S. population from 319 million (2014) to 417 million (2060)
  - Projected increase in aging population from 46 million (2014) to 98 million (2060)
  - By 2030, 1 in 5 Americans 65 and over

- **Fewer Physicians**
  - Projected shortfall of up to 94,700 physicians by 2025
  - Projected shortfall of up to 35,600 primary care physicians by 2025
  - Projected shortfall of up to 60,300 non-primary care physicians by 2025

- **Payment for Value / Outcomes**
  - Driven by increased patient costs and post-acute care strategies designed to reduce readmissions

- **Ubiquity of Technology**

- **Use of Telehealth Outside U.S.**
Benefits of Telehealth

- **Efficient, Cost-Effective Patient Care**
- **Collaboration Between Providers to Help Improve Patient Care**
- **Access to Specialty and Subspecialty Care (e.g., extending provider reach)**
- **Access for Patients in Underserved / Rural Locations**
- **Patient Satisfaction**
- **Cost / Penalty Avoidance (Value-Based Purchasing)**
Usage of Telehealth Services

- Patient Care
- Remote Patient Monitoring
- Medical Education of Providers
- Consumer Health Information
# Telehealth Modalities

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<thead>
<tr>
<th>Telehealth Modality</th>
<th>Description</th>
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<tr>
<td><strong>Real Time</strong> (&quot;Synchronous&quot;)</td>
<td>Provider and patient communicate live via videoconferencing. Commonly used for providing, e.g., telebehavioral health, telehomecare, and telecardiology services. Enables remote consultations (teleconsults) between a variety of primary and specialty health care professionals.</td>
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<td><strong>Store &amp; Forward</strong> (&quot;Asynchronous&quot;)</td>
<td>Digital images, videos, audio, and/or clinical data are captured electronically and stored on a patient’s computer / mobile device, and then transmitted securely to a provider for later study or analysis. Commonly used for providing, e.g., teledermatology and telepathology services.</td>
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<td><strong>Remote Patient Monitoring</strong></td>
<td>Patient uses a system that remotely captures and feeds data / information from sensors and/or other monitoring devices / equipment to an external monitoring center so that providers can monitor the patient remotely. Commonly used for monitoring chronic health conditions, e.g., heart disease, COPD, diabetes, and asthma.</td>
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Legal / Regulatory Issues for Telehealth Providers
Legal / Regulatory Issues for Telehealth Providers

- Licensure
- Scope of Practice
  - Physician-Patient Relationships
  - Remote Prescribing
- Coverage and Reimbursement
- Privacy and Security
- Fraud and Abuse
- Professional Liability
Licensure – An Overview

“States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety, and other valid interests, they have broad power to establish standards for licensing practitioners and regulating the practice of professions.” Goldfarb v. Virginia State Bar, 421 U.S. 773, 792 (1975).
Health care professionals who provide services via telehealth modalities generally are subject to the licensure rules of: (1) the state(s) in which their patients are physically located; and (2) the state(s) in which they (the professionals) are practicing.
Licensure and Telehealth
Licensure and Telehealth

Initiatives Attempting to Address Telehealth Licensure Issues

- When thinking about potential multi-state telehealth arrangements, consider where the health care professionals would need to be licensed:
  - Some states explicitly address the issue
  - Some states indirectly address the issue, either by including the act of diagnosing or rendering treatment through “electronic or other means” as part of the practice of medicine or by using broader language such as “by any means or instrumentality” to subject out-of-state practitioners to the state’s medical licensing laws
  - Some states do not address the issue at all

- Various initiatives have attempted to address telehealth licensure issues:
  - Interstate Compacts (e.g., FSMB, NCSBN)
  - Congressional Initiatives (114th Congress)
    - Veterans E-Health & Telemedicine Support (“VETS”) Act of 2015 (H.R. 2516 / S. 2170)
    - Telemedicine for Medicare (“TELE-MED”) Act of 2015 (H.R. 3081 / S. 1778)
  - Variety of State Legislative Initiatives
FSMB Interstate Medical Licensure Compact

- Designed to *facilitate* physician licensure portability and practice of interstate telemedicine services ([http://licenseportability.org](http://licenseportability.org))
- Would create an *additional licensure pathway* through which physicians could obtain expedited licensure in Compact-participating states
- Intended to *complement, not supersede*, existing authority of state medical boards
- Compact Commission working to establish an administrative framework
- Conceptually similar to Nurse Licensure Compact ([https://www.ncsbn.org/nlc.htm](https://www.ncsbn.org/nlc.htm))
APRN Model Compact

- Approved May 2015 by Special Delegate Assembly of the NCSBN (https://www.aprncompact.com/)
- Would allow APRNs to hold a single multistate license with a privilege to practice in other Compact states
- Requires enactment by at least 10 states in order to be effective (currently, 2 states have enacted)
- Would authorize APRN multistate license holders to practice independent of a supervisory or collaborative relationship with a physician, and would extend them prescriptive authority for non-controlled prescription drugs
Scope of Practice – An Overview

- Generally, a health care practitioner’s “scope of practice” delineates what members of the profession may do and places limits upon the functions that members of the profession may lawfully perform.

- Each state has its own laws, regulations, and governing bodies that craft and enforce particular scope of practice requirements.

- Health care professions with defined scope of practice requirements include:
  - Physicians
  - Nurses
  - Pharmacists
  - Social Workers
  - Emergency Medical Services Personnel
  - Midwives
Scope of Practice – Establishing the Physician-Patient Relationship

- Traditionally, establishing a physician-patient relationship has required at least an initial in-person encounter between a physician and a patient.

- Increased use of telemedicine technologies raises questions regarding this traditional view of physician-patient relationships:
  - When is a physician “consulting”?
  - When is a physician making a “diagnosis”?
  - When is a physician “treating” a patient?
Scope of Practice – Establishing the Physician-Patient Relationship

Establishing a physician-patient relationship depends on:

- Patient’s medical history
- Physician’s affirmative acts, e.g., examining, diagnosing, treating, or agreeing to treat the patient

Satisfying the minimum standard of care

Utilizing online web portals designed to diagnose and treat patients without a physical examination

Collective Analysis:
- Legal
- Risk Management
- Insurance
- Quality

Utilizing online web portals designed to diagnose and treat patients without a physical examination
FSMB Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine

- Adopted by FSMB in April 2014; replaced FSMB’s 2002 Model Guidelines for the Appropriate Use of the Internet in Medical Practice

- Provides that in some situations, telemedicine technologies can be used in lieu of in-person care, but also provides guidance on key relevant practice issues (e.g., continuity of care, maintaining a patient’s medical record, necessary disclosures)

- On establishing the physician-patient relationship:
  - Fully verifying and authenticating location;
  - To extent possible, identifying requesting patient;
  - Disclosing and validating provider’s identify, credentials, etc.;
  - Obtaining appropriate consents from requesting patients after disclosures regarding delivery models, treatment methods / limitations, etc.
States have different approaches to regulating remote prescribing:

- Requiring an in-person evaluation or physical examination before prescribing online
- Some states explicitly require in-person exams
- Other states are not so explicit (can physical exam be provided by other means?)
- Permitting physicians to prescribe via telehealth modalities only if there is a preexisting patient relationship even if physician is licensed in the state where patient is physically located
- Prohibiting prescribing based solely on information from an online questionnaire
- Regulating online prescribing through pharmacy laws
- Liberalizing prescribing laws (e.g., VA)
Coverage and Reimbursement – Medicare

Limited Coverage

- Beneficiaries are responsible for co-insurance and deductible payments
- Only certain codes are reimbursed
- Encounters may be performed at distant sites only by certain identified practitioners (e.g., physicians, NPs, PAs)
- Beneficiaries must be present and encounters must involve interactive audio and video telecommunications providing real-time communication between the practitioner and the beneficiary
- Beneficiaries must be seen at certain, identified originating sites (e.g., hospitals, physicians’ offices, FQHCs)
  - In very rural counties

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Coverage and Reimbursement – Medicaid

States have the option / flexibility to determine whether to cover telehealth services and what types of services to cover.

To date, 48 states and D.C. provide at least some coverage of and reimbursement for telehealth services.

States not required to submit a separate SPA for coverage of or reimbursement for telehealth services, if they reimburse for telehealth services in the same way / amount they do for face-to-face services / visits / consultations.

States are responsible for ensuring access and covering face-to-face visits / examinations by “recognized” practitioners / providers in those parts of the state where telehealth services are not available.
Coverage and Reimbursement – Private Payers

Many leading private insurers provide coverage and reimbursement for telemedicine services, although these policies vary

- Private pay “pioneers” include:
  - Blue Cross Blue Shield
  - CIGNA
  - United Healthcare

A growing number of states have or are in the process of enacting so-called “parity” laws

- Generally require health insurers to cover and provide reimbursement for services provided via telemedicine “in a comparable manner” to how the payer would for the same services provided in person
- 25 states and counting (e.g., CA, GA, HI, MD, MI, OR, VA)
Privacy and Security Generally

HIPAA
- Privacy Rule
- Security Rule
- Breach Notification

State Privacy and Security Laws

FTC Act
Telehealth Privacy and Security Issues

- Sharing data and management responsibility with other providers
- Determining what should be maintained as part of the medical record
- Complying with privacy laws in multiple states
- Incorporating telehealth-specific risks into compliance program
- Using web-based platforms (Skype, etc.) to deliver care in a compliant manner
- Transmission security
- Breach notification (verifying breaches)
- Providing HIPAA training and education for telehealth providers
- Entering into BAAs with technical providers (non-Covered Entities) supporting provision of telehealth services
- Managing presence of non-clinical personnel (non-Covered Entities) supporting provision of telehealth services
- Distributing Notice of Privacy Practices to telehealth patients
Fraud and Abuse Considerations

Underlying Principles

✓ Patient care and safety
✓ Appropriate utilization of therapies and tests
✓ Elimination of industry influence from patient care
✓ Independence of medical judgment
✓ Containment of costs
  • Pay for only legitimate expenses
  • Not waste taxpayers dollars
Fraud and Abuse Laws in a Nutshell

- The Anti-Kickback Statute prohibits “remuneration” in exchange for referrals, purchases, orders, or recommendations for purchases of items or services directly or indirectly reimbursed by federal health care programs.

- The Stark Law prohibits physician referrals of “designated health services” for Medicare / Medicaid patients if the physician (or an immediate family member) has a “financial relationship” with the entity.

- The False Claims Act prohibits the submission (or causing the submission) of false or fraudulent claims to governmental payers.
  - Anything downstream from an AKS or Stark violation is a false claim

- States may have their own versions of each of these laws, some of which are stricter than the federal standards and some that apply to all payors, not just government payors (“all payor laws”).
## Fraud and Abuse Considerations

*Application to Providing Telehealth Services*

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<th>Be Mindful Of . . .</th>
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<tr>
<td>• Equipment used to provide telehealth services can be costly</td>
<td>• Anti-Kickback Statute</td>
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<td>• Distant site providers may be offered free or discounted equipment from originating site providers, other providers, or vendors</td>
<td>• Physician Self-Referral Law (“Stark Law”)</td>
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<tr>
<td>• Receipt of free or discounted services by health care providers may implicate federal and state fraud and abuse laws</td>
<td>• False Claims Act</td>
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<td>• State-Specific Equivalents</td>
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OIG Advisory Opinion No. 11-12 (2011)

*Providing Neurology Treatments via Telehealth Technology*

- OIG allowed a hospital to share telemedicine resources with another hospital, in the interest of promoting new models of consultation and improving patient care by reducing unnecessary patient transfers.

- OIG recognized that the hospital’s Stroke Center and community hospitals that were part of the proposed arrangement are potential sources of referrals for each other, but concluded that the risk of an improper payment for such referrals was low, based on several factors:
  - Proposed arrangement would not require community hospitals to make referrals to the Stroke Center.
  - Neither the volume or value of any actual or potential referrals would influence the Stroke Center’s selection of participating community hospitals.
  - Proposed arrangement would be unlikely to generate additional referrals to the benefit of the Stroke Center or community hospitals, but instead would primarily benefit patients.
  - Neither party would be required to market on behalf of the other, and each would bear its own costs for any marketing activities.
Telehealth Professional Liability – Many Unresolved Questions

Common liability questions / issues:

**Telehealth Informed Consent**
- Does my state require informed consent?
- What are the standards of care?

**Supervision**
- When is it medically appropriate to supervise other practitioners via telehealth modalities?
- What about supervision of machines and devices that provide medical services?

**Liability Insurance**
- Are telehealth services covered under my existing policy?
- What would adding coverage for telehealth services entail?

**Practice Standards and Protocols**
- Is telehealth sufficiently different from usual care as to require its own protocols and standards?
- Do established guidelines exist?

**Physician-Patient Relationship**
- How is it defined for purposes of scope of practice?
- How is defined in relation to liability claims?

**International Telehealth**
- Will I be covered while providing services internationally?
- Who has jurisdiction over international telehealth services?

**Telehealth Industry**
- Is telehealth changing the nature of the relationship between patients and providers?
- Is telehealth fundamentally different from traditional forms of health care?
A Focus on Telemental Health
Mental Illness in the U.S.  
*Prevalence, Costs, and Access to Treatment*

- About half of all Americans will meet criteria for a diagnosable psychiatric disorder in their lifetime.

- According to the Substance Abuse and Mental Health Services Administration (“SAMHSA”), mental illness treatment costs are $100 billion annually, accounting for 6.4% of the $1.6 billion spent on health care in the U.S. annually.
  - Indirect costs (e.g., lost earnings, disability benefits) of mental illness are much higher than the direct costs.

- Approximately 91 million adults live in areas of “psychiatry shortage” in the U.S.

- Other factors complicate access to mental illness treatment.
  - Mental health practitioners (esp. psychologists) aging out of practice
  - Mental health practitioners refusing to accept insurance
Benefits of Telemental Health

- Increased access to mental health practitioners
- Breaking down traditional barriers of distance, time, and stigma
- Giving mental health practitioners increased freedom / flexibility and decreasing overhead associated with providing services
Regulatory Obstacles to Telemental Health

_Different Considerations, or More of the Same?_

- Multitude of Licensure Types
- Legal / Ethical Considerations
- Cultural / Lingual / Diversity Issues
Developments in Telemental Health

What Are States Doing?

- **California**: The Board of Psychology’s *Notice to California Consumers Regarding the Practice of Psychology on the Internet* addresses various regulatory requirements, including that practitioners must have current, valid licenses to practice in California.

- **Colorado**: The State Board of Psychologist Examiner’s Teletherapy Policy (§ 30-1) provides guidance regarding psychotherapy through electronic means, which includes compliance with all provisions in the state’s Mental Health Practice Act, including licensure.

- **Florida**: The Board of Psychology has issued opinions stating that teletherapy constitutes the practice of psychology requiring Florida licensure (06-0976), and that a Florida-licensed psychology residing in Michigan could provide telepsychology services to patients in Florida (12-0324).

- **Louisiana**: The State Board of Examiners of Psychologists’ *Telepsychology Guidelines* (eff. Jan. 2015) require that practitioners are “aware of and in compliance with Louisiana psychology licensure laws and rules”.

- **Nevada**: Assembly Bill No. 292 (eff. July 2015) outlines the Board’s policy regarding telepsychology, stating that practitioners who provide services through telehealth to patients located in Nevada are subject to the laws and the jurisdiction of the state, including licensure requirements, regardless of the location from which the practitioner provides such services.
Telemental Health Privacy and Security Issues

Patient-Provider Interactions

Patient Records
Questions and Answers
Presented by

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