

Morgan Lewis

FAST BREAK:

TELEHEALTH

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Agenda

- What is “telehealth”?
- Primary legal issues in telehealth
 - Licensure of providers
 - Telehealth reimbursement
 - Corporate practice and fraud/abuse
 - HIPAA



What is Telehealth?

- **Different things to different people**
 - No single definition or usage of telehealth
 - Often used interchangeably with telemedicine
- **In essence, remote exchange of healthcare information**
 - Live A/V
 - Remote monitoring
 - Asynchronous communications
 - Medical devices
 - Other communications?



What is Telehealth?

- **Who is thinking about telehealth?**

- These days: just about everyone

- **Commercial Payors**

- Insurers
- MCOs
- Employer Plans

- **State Government**

- Medical Boards
- Pharmacy Boards
- Nursing Boards
- Medicaid Agencies

- **Federal Government**

- CMS
- HRSA
- DEA
- FDA

- **Telecomm Companies**

- Software companies
- Management companies
- Startups
- Fortune 500s
- Device manufacturers

- **Providers**

- Hospitals
- ACOs
- Physicians
- Home health and hospice
- Just about all providers

State Professional Board Requirements

- **Telehealth Encounter Requirements**

- Permitted modalities
- Site of service
- Tele-presenter or on-site health care provider
- Informed consent (written or verbal)
- Ensuring identity of patient & practitioner

- **Internet Prescribing & Telepharmacy**

- Long-standing concern of improper prescribing through internet questionnaires in support of “pill mills”
- Ryan Haight Online Pharmacy Consumer Protection Act

State Professional Board Requirements

- **Licensure**

- Required for each state in which practitioner and/or patient is located
- Potential for civil and/or criminal penalties
- Special purpose licenses for telemedicine
 - Interstate Medical Licensure Compact
 - Interstate Nurse Licensure Compact

- **Establishment of Physician-Patient Relationship**

- Traditionally, required an in-person evaluation
- Telehealth is challenging that thinking



Telehealth Reimbursement

- **Commercial**

- Insurance policies vary widely in telehealth coverage
- Some insurers have determined significant value in telehealth services and will cover a wide array of services
- Several states (~35) have implemented “parity” laws requiring commercial insurance coverage of telehealth services equal to coverage of traditional face-to-face services

- **Payors Increasingly Aligning With Telehealth Companies**

- Provide additional member benefits
- Decrease strain on brick-and-mortar providers
- Done through acquisitions or joint ventures

- **Employer Groups Also Exploring Telehealth Options**

Telehealth Reimbursement

- **Medicare**

- Medicare coverage of telemedicine services is narrow
- Complex Medicare billing issues and beneficiary liability questions
- Program limited by legislation, but new legislation and various demonstrations pending:
 - Medicare Telehealth Parity Act of 2015
 - Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act - S. 2484 (introduced February 2, 2016)
 - State demonstrations under Capitated Financial Alignment Model for Medicare-Medicaid Enrollees (NY HHA and VA Dual Eligible Integrated Care)
 - State demonstrations under Federal Telemedicine Demonstration (HI and AK)

- **Medicaid**

- More flexibility than Medicare, but results in highly variable coverage criteria
- Most states allow some type of telehealth coverage

Corporate Practice Doctrine

- **Statutory, Common Law, and “Other” Restrictions on Who Can own or Operate a Medical Practice or Engage in the Provision of Licensed Professional Health Care Services**
- **Varies From State To State**
- **Adopted in Many States**
 - For example: California, Illinois, New York, Texas
 - Requires clinical entity to be owned by a licensed health care professional or be a licensed health care entity (e.g., hospital, managed care organization)
- **Requires an Alternative Form of “Ownership” and Control**
 - Practice entity
 - Practice management company
- **How Does this Affect Telehealth Companies?**

Fraud & Abuse Laws

- **Federal and state**

- Kickback laws
- Self-referral laws (Stark)
- False claims laws
- Fee-splitting (state only)

- **Examples of What Can Trigger Scrutiny**

- Marketing/advertising
- Financial interests in entity receiving referral
- Joint promotion
- Non-compliance with billing rules
- Billing for services that lack medical necessity
- Dividing payment between practitioner and software company on per patient/per encounter basis

HIPAA & State Privacy Laws

- **HIPAA** – the one healthcare law that most consumers know
 - Does it apply?
 - Notice of privacy practices
 - Business Associate Agreements
- **State Privacy Laws**
 - May be more onerous than HIPAA
- **Data Security on Everyone's Mind**
- **OCR Audits Not Only of CEs but also Business Associates**



Evolution of the Telehealth Landscape

- **A number of systemic features of current healthcare regulatory environment raise challenges for effective telehealth practice**
 - Laws were enacted when interaction between provider and patient was solely face-to-face and many have not been fully updated
 - States have interest and responsibility in protecting the health and welfare of citizens, which delays acceptance of new practice platforms
- **However, efforts to quickly bridge gap given:**
 - Consumer demand
 - Enhanced access
 - Lower cost
 - Largely positive clinical feedback
 - Dwindling supply of primary care physicians

Challenges in Telehealth Implementation

- **Understand where you fit into the telehealth regulatory scheme**
 - Hospital? How can telehealth help you keep patients from being readmitted?
 - Device manufacturer? Is your wearable regulated by the FDA?
 - Software developer? What are the hurdles for employing physicians to practice through your app?
 - Insurer? Do state parity laws affect your payment policies?
 - Physician or practitioner? Is telehealth right for you and your patients?
- **Significant grey areas currently exist where regulators have not yet devised a framework for telehealth**
 - Though legislation/regulations in many states is actively being considered

Thanks!



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