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THE HEALTHCARE REGULATORY LANDSCAPE FOR TELEHEALTH

TECHNOLOGY MAY-RATHON

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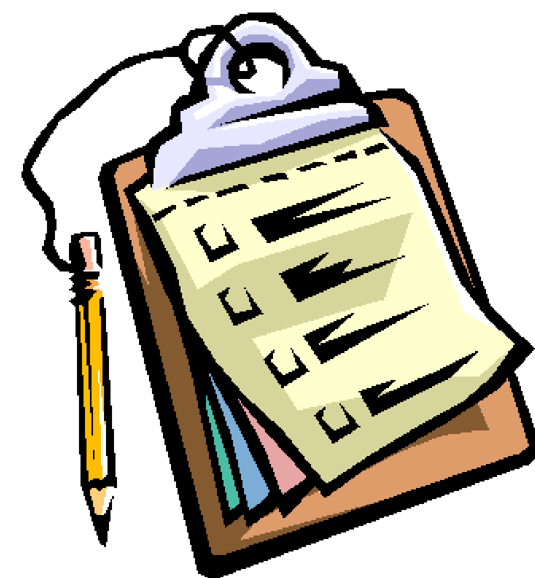
Agenda

- The current regulatory landscape
- Recent and pending legislation
- Third-party payor reimbursement
- Recent litigation and enforcement actions



THE CURRENT REGULATORY LANDSCAPE

Defining Telehealth

- **There is no single definition or usage of "telehealth"**
  - A "professional service via an interactive telecommunications system" – Centers for Medicare & Medicaid Services, at 42 C.F.R. 414.65(a)
  - "[T]he use of technology to deliver health care, health information or health education at a distance" – Health Resources Services Administration
  - "[T]he use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status" – Commercial Payor

- **Often used interchangeably with "telemedicine"**
  - In some definitions, telehealth is a broader reference to all health care treatment, prevention, education, and support activities delivered remotely, while telemedicine refers more specifically to a clinical interaction between a patient and a health care provider

Telehealth for this Discussion

- This discussion will focus on the healthcare regulatory environment for clinical interactions between a patient and a health care provider that occur remotely via electronic communications.

- For example:
  - **Store-and-forward** – asynchronous technology whereby patient provides relevant medical information to professional remotely who then uses information to form diagnosis and treatment plan
  - **Remote monitoring** – technology providing remote professional with medical data from personal device held/used by patient, either real-time or asynchronously (i.e. cardiac monitors)
  - **Interactive audio-visual** – provides real-time, interactive encounter between individual and professional through videoconference or similar function (including fixed (*i.e.* kiosk, computer) and mobile (*i.e.* smart phone) technology)

The Players

- **Healthcare providers**
- **Payors**
  - Government
  - Commercial
  - Employers
- **Telehealth platform/infrastructure companies**
  - Management
  - Marketing
  - IT
  - Hardware
  - Software
- **Federal and state regulatory agencies**

Healthcare Regulatory Issues

- **Corporate practice doctrine**
- **State professional board requirements**
  - Licensure
  - Establishment of physician-patient relationship
- **Federal and state fraud and abuse laws**
  - Anti-kickback & beneficiary/patient inducement
  - Self-referral
  - Fee-splitting
  - False claims
- **HIPAA and state privacy laws**

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?

State Professional Board Requirements

- **Licensure**
  - Required for each state in which practitioner and/or patient is located[m2]
  - Complications in providing telehealth services in multiple states
  - Potential for civil and/or criminal penalties
  - Exceptions (*e.g.,* physician-to-physician consultations, emergencies)
  - Special purpose licenses for telemedicine

- **Establishment of physician-patient relationship**
  - Traditionally, required an in-person evaluation

Slide 9

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m2 Which states base it on where practitioner is located?
mp073587, 5/10/2016

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”

Examples of State Guidelines

- **California:** Telehealth means the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while the patient is at the originating site and the health care provider is at a distant site. Telehealth facilitates patient self-management and caregiver support for patients and includes synchronous interactions and asynchronous store and forward transfers. CA Bus. & Prof. Code Sec. 2290.5

- **Virginia:** Telemedicine services means the use of electronic technology or media, including interactive audio or video for the purpose of diagnosing or treating a patient or consulting with other health care providers regarding a patient's diagnosis or treatment. 'Telemedicine services' does not include an audio-only telephone, electronic mail message, facsimile transmission, or online questionnaire. Va. Code 38.2-3418.16

Fraud & Abuse Laws: Kickback

- **Federal and state**

- **Examples of what can trigger Anti-Kickback Law scrutiny**
  - Marketing/advertising
  - Slotting fees
  - Joint promotion
  - Technology licensing
  - Referral programs

- **Safe harbors & exceptions**

Fraud & Abuse Laws: Self-Referral

- **Federal and state**

- **What triggers scrutiny:** When a physician or other referring practitioner (or their immediate family members) has a financial interest (*i.e.*, investment and/or compensation arrangement) with the entity that receives the referral

- **Federal Physician Self-Referral Law (Stark Law)**
  - Applies to Medicare
  - Exceptions for e-prescribing and EHR arrangements

- **State self-referral laws**
  - Can be broader in scope than the Stark Law

Fraud & Abuse Laws: Fee-splitting

- **State law**

- **In General:** Prohibits a health care provider from sharing their professional fees with a referral source
  – Marketing activities may be construed to be a referral

- **What triggers scrutiny:** Because providers typically don’t own the telehealth platform, increased risks of “fee-splitting” concerns
  – Portion of payment goes to Telehealth platform provider and thus fee is “split” between physician and Telehealth company
  – Per consultation or per visit fees
  – Percentage of collections
  – Flat fixed fees (monthly or other timeframe)

Fraud & Abuse Laws: False Claims Act

- **Federal and state**
  - Federal False Claims Act applies to federal health care programs
  - State false claims laws may apply to all or certain specified payor types (*e.g.*, Medicaid, commercial)

- **What triggers scrutiny:** When a person knowingly submits a false claim for payment
  - Upcoding
  - Billing for services not rendered
  - Billing for services that lack medical necessity
  - Non-compliance with billing rules

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

RECENT & PENDING LEGISLATION

Evolution of the Telehealth Landscape

- A number of systemic features of current healthcare regulatory laws raise challenges for effective telehealth practice
  - Laws were enacted when interaction between physician 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
  - These challenges include:
    - Practicing medicine without a license (or beyond state borders)
    - Establishing a physician-patient relationship
    - Lawfully prescribing medications
    - Ensuring patient's informed consent
    - Establishing both the practitioner and patient's identity to each other

Interstate Medical Licensure Compact

- Interstate Medical Licensure Compact (IMLC) provides for model legislation in states to facilitate the licensure of physicians in multiple states through common rules and procedures

- Promises a streamlined, time saving licensing process, but is not a national medical licensure program

- Model Act enacted in 12 states (mostly rural western-central U.S.) and introduced in 14 (central U.S. and parts of Eastern Seaboard)

- Not yet implemented

Interstate Nurse Licensure Compact (NLC)

- Promoted by the National Council for State Boards for Nursing
- Differs from Interstate Medical Licensure Compact
  - The NLC is a mutual recognition licensure model
    - If nurse holds a license in his/her home state, it is recognized in the other compact states – no additional applications required
    - Think of a driver's license
  - 25 States have adopted the NLC
- Early successes, but adoption by states has slowed
- Applies only to RNs and LPNs
- APRN Compact

Ryan Haight Online Pharmacy Consumer Protection Act

- Enacted in 2008, amends the Controlled Substances Act by establishing requirements to prescribe controlled substances over the Internet.

- Requires:
  - A valid prescription for a legitimate medical purpose and requires at least one in-person medical evaluation of the patient
    - Exception for telemedicine
    - Requires interactive telecommunications
    - Precludes:
      - An online medical questionnaire
      - Store and forward

THIRD-PARTY PAYOR REIMBURSEMENT

State Parity Laws

- Insurance policies vary widely in Telehealth coverage
  - Some insurers have determined significant value in Telehealth services and will cover a wide array of services
  - Others have not yet developed a comprehensive Telehealth coverage framework – may result in denials or onerous prior authorization requirements
- Several states have implemented parity laws requiring commercial insurance coverage of Telehealth services equal to coverage of traditional face-to-face services
- Recent development – laws have not yet had significant effect on access to Telehealth services
- However, as coverage increases (through legal mandate or financial drivers for insurers), use of telehealth services will also increase

Private Payors

- Parity Laws: Growing number of states have enacted laws that require coverage for telehealth services. 32 states + DC.
  - Depending on the state, payments for telehealth services must be equivalent to, be on the same basis as, or be equal to the payment rate for an in-person visit

- Payors are increasingly aligned with telehealth companies
  - Acquisitions
  - Joint Ventures

- Employers
  - Including for state employees

Medicare Coverage

- Medicare coverage of telemedicine services is narrow
  - Must be conducted through live, interactive videoconferencing
  - May only be provided to patients in a rural Health Professional Shortage Area (HPSA) or in a county outside of a Metropolitan Statistical Area (MSA)
  - The patient must be at an "originating site," which includes physician offices, hospitals, and other facilities, but does **not** include a patient's home
  - Limited to certain CPT codes (certain office visits, psychotherapy, nutrition and behavior counseling, etc.)
- CMS slowly embracing Telehealth, but cannot cover at same level as commercial insurers without legislative change
- Providing Telehealth services to Medicare beneficiaries raises "Advanced Beneficiary Notice" issues relating to financial responsibility for services
- Medicare also covers certain remote monitoring technologies (*e.g.,* cardiac)

Medicare Coverage

- Greater flexibility with Medicare Advantage (Part C)
- Affordable Care Act
  - State demonstrations under Capitated Financial Alignment Model for Medicare-Medicaid Enrollees
  - New York:
    - Coverage in connection with home health services (includes payment for telehealth and equipment installation)
  - Virginia:
    - Waives Medicare geography and technology restrictions
    - Allows telehealth coverage in urban and rural areas
    - Permits videoconferencing, store-and-forward and remote patient monitoring
- 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)

Medicaid

- **More flexibility than Medicare**
- **Most state Medicaid programs cover some form of telehealth services**
  - Type of service / permitted technologies
  - Location of service
  - Eligible patients
  - Eligible providers
  - Distance between patient and provider
- **Coverage varies by state**
- **Greater flexibility with Medicaid managed care**

LITIGATION & ENFORCEMENT

Teladoc

- In 2011, the Texas Medical Board (TMB) sent a letter to Teladoc threatening disciplinary actions against Teladoc physicians for prescribing dangerous drugs/controlled substances without first establishing a proper professional relationship with the patient (i.e., a face-to-face encounter).
- **December 31, 2014 - Texas Court of Appeals.**
  - Teladoc prevails.
  - Court holds that the TMB rule was invalid.
- **January 2015**
  - TMB issues an emergency rule limiting use of telephones
  - Teladoc sues TMB claiming that emergency rules were not justified
- **April 2015 – U.S. District Court**
  - Teladoc sues TMB alleging anti-trust violations
- **December 2015 - TMB motion to dismiss denied**
  - TMB appealed to Fifth Circuit Court of Appeals

In Other News…

- Not just Texas

- State medical boards asking telehealth companies to present a description of their corporate structure, fee arrangements, operations and scope of services.
  - Inquiries occurring under the radar
  - Seeing increased focus on management fee-arrangements
  - Most enforcement actions are years old and involve "pill mill" arrangements

- OCR HIPAA audits

Challenges in Telehealth Implementation

- How to handle these various challenges
  - Approach varies based on specific type of Telehealth platform at issue (interactive videoconference presents different operational hurdles than store-and-forward)
  - Above all else, buy-in from physicians is critical
    - Ideally, their work should be the same, just performed through a different medium
    - Typically, their licensure is on the line – physicians bear most risk for engaging in Telehealth practice
  - Significant grey areas currently exist where state regulators have not yet devised a framework for telehealth
    - Though legislation/regulations in many states is actively being considered

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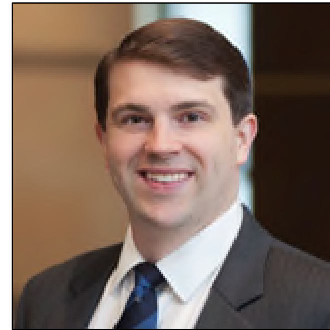

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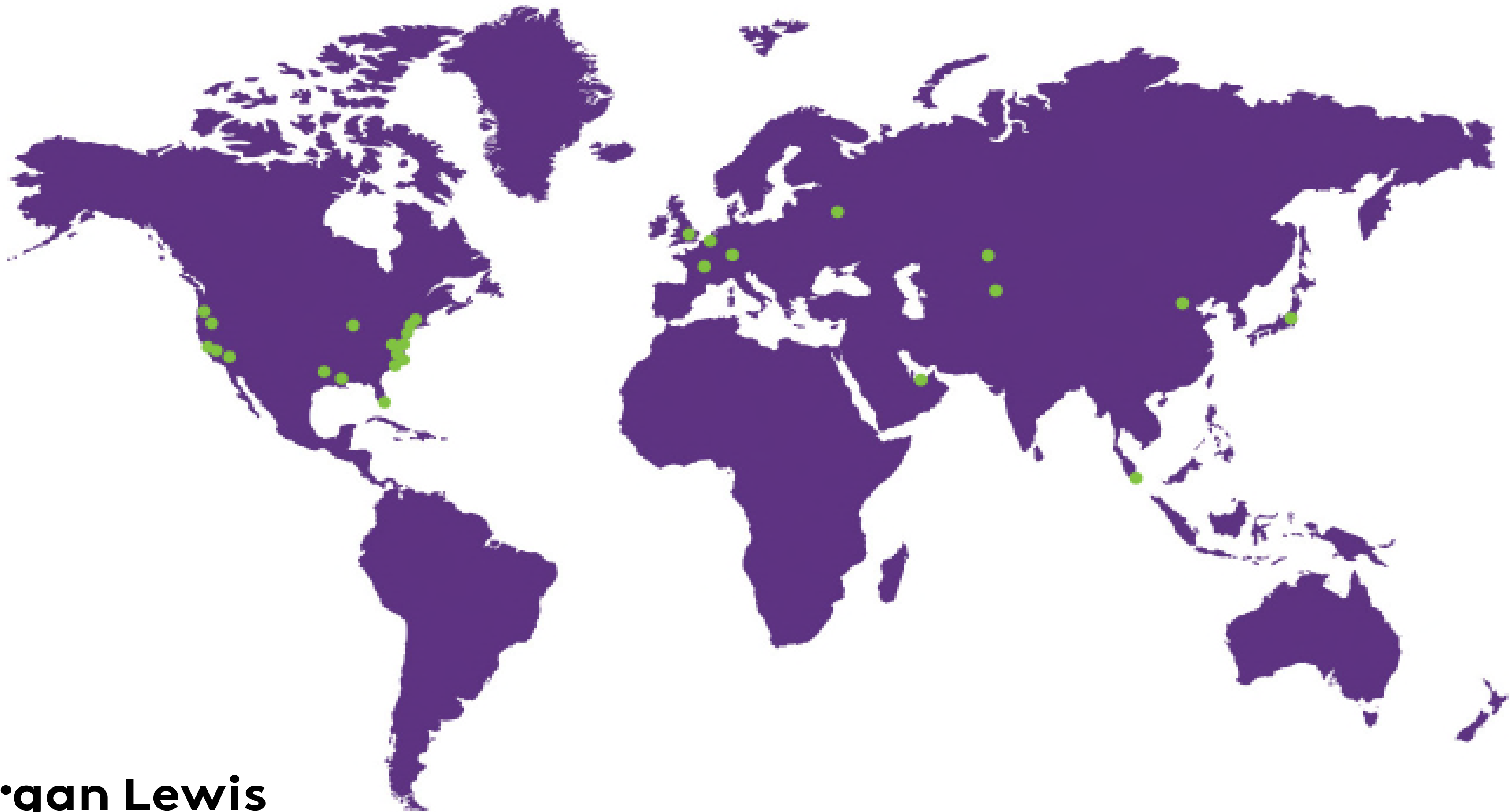

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