



Morgan Lewis

STILL BEING PAVED: RULES OF THE ROAD FOR TELEHEALTH

Jacob Harper
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Morgan Lewis Technology May-rathon 2018

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This year is our 8th Annual Tech May-rathon and we are offering over 30 in-person and virtual events on topics of importance to our clients including privacy and cybersecurity, new developments in immigration, employment and tax law, fintech, telecom, disruptive technologies, issues in global tech and more.

A full listing and of our tech May-rathon programs can be found at <https://www.morganlewis.com/topics/technology-may-rathon>

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What is Telehealth?

- **Different things to different people**
 - No single definition or usage of telehealth
 - Often used interchangeably with telemedicine
 - Federal, state, and private payors have different paradigms
 - Occasionally, same entity may use term in different ways
- **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?

Commercial Payors

- Insurers
- MCOs
- Employer Plans

State Government

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

Federal Government

- CMS
- HRSA
- DEA
- FDA
- VA

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
 - But changes pending in Congress

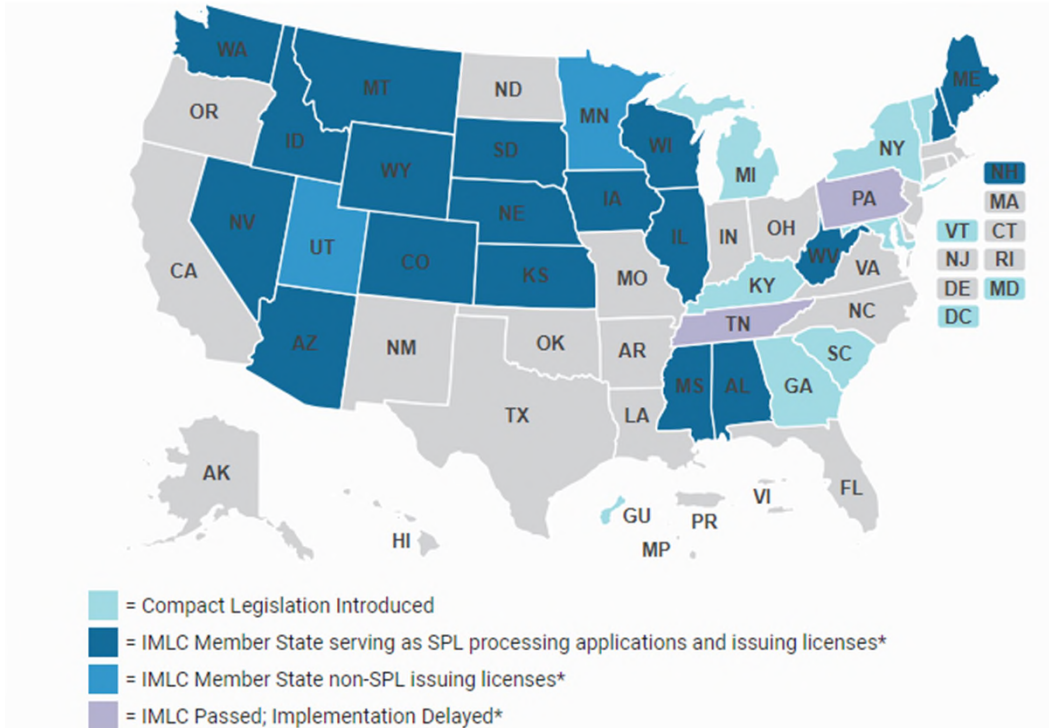
State Professional Board Requirements

- **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



State Professional Board Requirements

- ILMC



(Source: www.imlcc.org)

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, which come in two flavors:
 - requiring commercial insurance coverage of telehealth services for traditional face-to-face services covered by that insurance product
 - Requiring telehealth coverage *to the same extent* as 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 and Benefits Administrators 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)
 - New legislation frequently proposed

- **Medicaid**

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

Telehealth Reimbursement

- **Increasing Scrutiny of Telehealth Payments**
- **April 5, 2018 Report by OIG**
 - Assessed 191,118 Medicare claims from 2014 and 2015 (worth \$13.8 million)
 - In a random sample of 100 claims, 31 did not meet Medicare requirements
 - 24 for non-rural originating sites
 - 7 billed by ineligible institutional providers
 - 3 for services at unauthorized originating sites
 - 2 for using unallowable means of communication
 - 1 claim provided by a physician located outside the United States
- **Additional targeted enforcement will follow, but Congress at the same time is signaling liberalization of telehealth coverage**

Fraud & Abuse Laws

- **Federal and state**

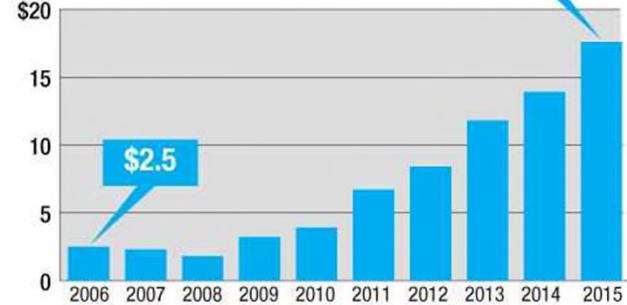
- Kickback laws
- Self-referral laws (Stark)
- False claims laws
- Fee-splitting (state only)

- **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

The increasing, but small, amounts Medicare has paid for telehealth

\$ In millions



Source: CMS

via Modern Healthcare

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

Evolution of the Telehealth Landscape

- **While cash pay, private insurance, and Medicaid set the pace for telehealth reimbursement, Congress/CMS recognizing importance of telehealth**
- **Bipartisan Budget Act of 2018 removes certain limitations from Medicare coverage for particular conditions starting in 2019**
 - ESRD can be provided in a patient's home
 - Telestroke services not required to be in a HPSA/rural area
- **Medicare Advantage (managed care) also allowing plans to include telehealth services not usually covered by Medicare in 2020**

Challenges in Telehealth Implementation

- **Understand where a particular entity/individual fits 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

Challenges in Telehealth Implementation

But...

We're getting there.

Biography



Jacob Harper

Washington, D.C.

+1.202.739.5260

jacob.harper@morganlewis.com

Twitter: [@jacobjharper](https://twitter.com/jacobjharper)

[LinkedIn](#)

Jacob Harper's practice involves counseling various stakeholders in the telehealth industry, including investors, start-ups, strategic partners, and health care providers, on the legal requirements for providing telehealth care. In addition to his telehealth practice, Jake advises hospitals, health systems, group practices, hospices, chain pharmacies, and private equity clients on compliance, fraud and abuse, and reimbursement matters. Jake also represents health care providers in DOJ and OIG investigations, self-disclosures to OIG and CMS, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

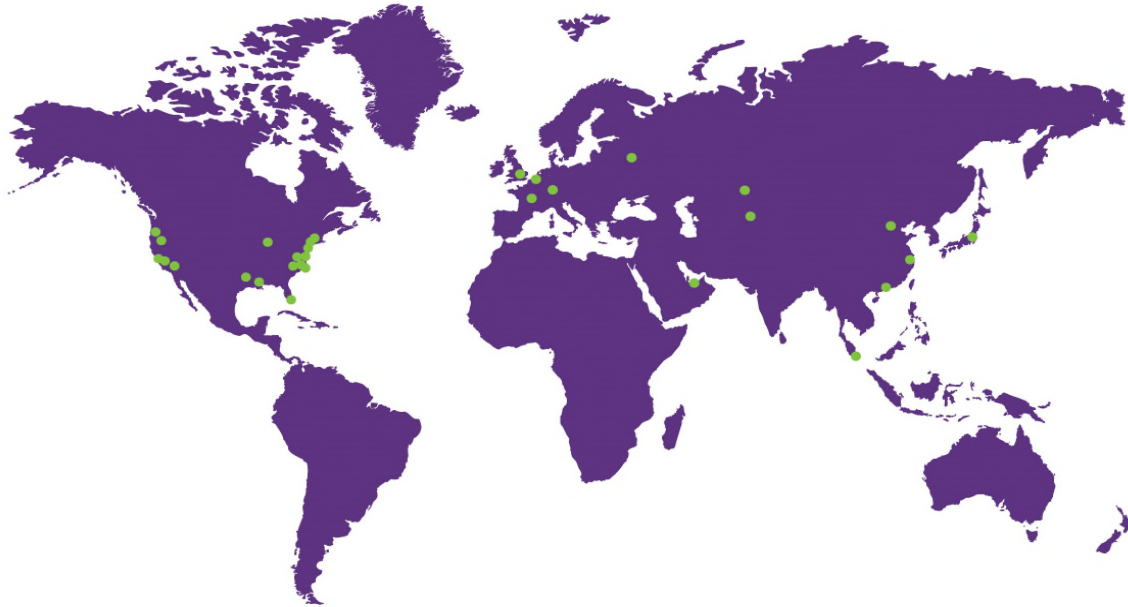


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