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North Country Telehealth Conference 2018

Operationalizing Telemedicine: Legal and Regulatory Issues

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Things We Won't Discuss



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Things We Won't Discuss

The Boston Red Sox clinch the American League East at Yankee Stadium (September 20, 2018)



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Things We Won't Discuss

The Boston Red Sox win the American League Division Series at Yankee Stadium, 3 Games to 1 (October 9, 2018)



Things We Won't Discuss

The Boston Red Sox win the 2018 WORLD SERIES



Things We Will Discuss

- State-specific considerations involving scope of practice, licensing, etc.
- Contracting considerations when providers engage telehealth services providers
- Health care fraud and abuse issues
- Corporate Practice of Medicine Doctrine
- Privacy (federal and state)

Structuring for State Legal Compliance: Diligence

- States may:
 - Prohibit foreign corporations from operating within their jurisdictions
 - Require professionals to be licensed in their jurisdictions to provide telehealth services
 - Restrict referral activity within telehealth networks through physician self-referral, anti-kickback, fee splitting and anti-markup statutes
 - Impose heightened patient privacy and security requirements
 - Impose specific clinical requirements when treating patients via telehealth

Telehealth Requirements for Providers

- Telehealth Modalities
- E-Prescribing
- Practitioner Licensure
- Documentation
- Informed Consent
- Patient Identification



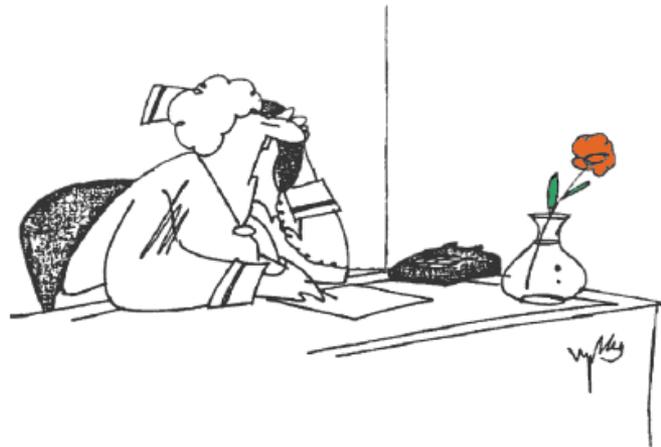
Telehealth Requirements: Telehealth Modalities

- How do you establish a practitioner-patient relationship?
 - **Industry standard is a live, two-way, audio-video interaction between the practitioner and the patient.**
 - Store and forward and remote patient monitoring are growing in popularity, and have CMS' support.
- Threshold questions to consider in each state:
 - What modalities does this state allow (and not allow)?
 - Can all services be provided via telehealth?
 - Can all practitioners provide services via telehealth?
 - Can patients only receive treatment via telehealth from certain locations, such as a doctor's office or a hospital? (E.g., NY)

Telehealth Requirements : Non-Video Modalities



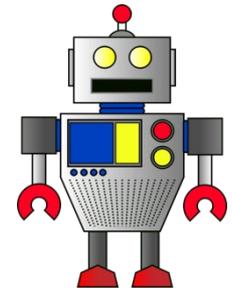
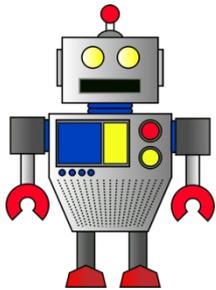
- E-mail, fax, text, phone call.
 - Check state law, but assume that these modalities alone without other communication (e.g., live audio-video communication) are not sufficient to **establish** a relationship. Rules for follow-up care will likely be different.
 - Some states have exceptions, like Maine. Always check.
- What worries regulators? See below.



"The doctor isn't in right now. When you hear the beep, please leave your name, number and a short diagnosis."

Telehealth Requirements : Non-Video Modalities

- Artificial intelligence (“AI”) and “smart questionnaires”
 - Some start up telehealth vendors are using these technologies to provide services, but that doesn’t mean they are legal.



“You can’t list your iPhone as your primary-care physician.”

Telehealth Requirements: E-Prescribing

- Clinicians can only prescribe medication pursuant to a valid practitioner-patient relationship.
- **Non-Controlled Substances: look to state law.**
- **Controlled Substances: look to state and federal law.**
 - State law is generally more strict concerning controlled substances.

Telehealth Requirements: Controlled Substances

- Ryan Haight Online Consumer Protection Act.
- SUPPORT for Patients and Communities Act
 - Special Telemedicine Registration
 - Medicare SUD Treatment and originating site restrictions
 - Medicaid SUD Treatment guidance forthcoming
- **Don't forget state law.**
 - Connecticut, no opioids.
 - California, new providers.
- Utilizing counsel will be very important as this unfolds.



Telehealth Requirements: Licensure

- The default rule is that a practitioner providing services via telehealth must be licensed in the **state in which the patient is located.**
- There are exceptions, such as Maine and Minnesota, but they usually still require registration with a state board.
- Interstate licensure compacts exist, but isn't as simple as it may seem.

Telehealth Requirements: Documentation

- Like any other medical visit, telemedicine encounters must be documented in accordance with state law, and recorded at times. Ensure that telehealth practices comply with applicable state law, including storage of records.
- Normal clinical best practices apply. Telemedicine is a way to deliver care, *not a unique discipline*.

Telehealth Requirements: Informed Consent and Identification

Some states require a practitioner to obtain a patient's informed consent before providing treatment via telehealth, e.g., California and Texas.



Some states require a practitioner to confirm a patient's identity before providing treatment via telehealth.

Operational Issues

- Proxy Credentialing
- Malpractice Insurance

Operational Issues: Proxy Credentialing

- Credentialing every provider who treats a patient at a facility via telemedicine can be expensive and extremely slow.
- CMS and the Joint Commission allow “originating sites” to rely on the credentialing of the facility at which the practitioner is located or the vendor providing services, instead of performing credentialing themselves.
- **ASK:** does each hospital utilizing proxy credentialing allow for proxy credentialing in its bylaws?

Operational Issues: Malpractice Insurance

- Malpractice insurance doesn't apply everywhere and may not cover services provided via telemedicine.
- Ask providers if their malpractice insurance covers the specific services that the practitioner is providing via telemedicine, and applies in every state in which patients they treat are located.

- Before engaging with a telehealth vendor/provider, your due diligence should determine whether the arrangement is in compliance in each of these areas in every state in which patients will receive treatment:
 - Telehealth laws
 - Fraud and abuse laws
 - Privacy/security laws
 - Corporate practice restrictions



Corporate and Regulatory Considerations: Telehealth Contracting Fraud and Abuse Laws

- **Federal Anti-Kickback Statute, 42 USC § 1320a-7b(b)**
 - Makes it illegal to knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals or generate federal health care program business
 - Violation may be found if *one purpose* is to induce referrals, even if there are other legitimate purposes for the payment
 - Criminal, intent-based statute
 - Civil monetary penalties (CMPs) as well as False Claims Act penalties triggered
 - Most states have corresponding provisions, some are more stringent (e.g., CA Bus. & Prof. Code § 650 applies regardless of payor type)
- **Federal Physician Self-Referral Law (“Stark”), 42 USC § 1395nn**
 - No referrals for Medicare business to an entity where a physician (or an immediate family member) has a financial relationship with the entity, regardless of intent
 - Applies to “designated health services,” which includes inpatient and outpatient hospital services
 - States have corresponding provisions that extent beyond Medicare (e.g., CA Bus. & Prof. Code § 650.01 applies regardless of payor type)
- **False Claims Act, 31 USC §3729 et seq., 18 USC § 287**
 - Prohibits the knowing submission of a false or fraudulent claim to the federal government
 - Knowing submission of a claim that results from a kickback or Stark law violation could render it false or fraudulent
- **Other laws are potentially implicated if a physician arrangement is not in compliance**
 - Potential exclusion from participation in government healthcare programs (42 USC § 1320a-7), civil monetary penalties (42 USC § 1320a-7a)



Closer look at the federal anti-kickback statute:

- Makes it illegal to knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals or generate federal health care program business
- Violation may be found if *one purpose* is to induce referrals, even if there are other legitimate purposes for the payment
- Criminal statute
- Most states have corresponding provisions, some are more stringent (e.g., NY)



Applicability to Telemedicine?

- Misconception #1: “I don’t need to worry about the anti-kickback statute, because there are no referrals in telemedicine...”
- Misconception #2: “I don’t need to worry about the anti-kickback statute, because the telemedicine services involved aren’t reimbursed by Medicare”



Corporate and Regulatory Considerations: Telehealth Contracting Fraud and Abuse Laws

- **Hypothetical #1:** Hospital enters into an agreement with a psychiatrist on staff to provide telemedicine services for patients that present in the ER with behavioral health issues. The psychiatrist also leases office space for her private practice in a hospital-owned medical office building and serves in a medical director role.
- **Hypothetical #2:** Hospital-affiliated physician practice contracts with telehealth vendor to: (1) license telehealth software; (2) provide support services (e.g., customer service for patients); (3) contract with or employ physicians to provide evening/weekend services.



- Anti-kickback risk can usually be mitigated through:
 - Fair market value (“FMV”) analysis of compensation and ownership arrangements; and
 - The avoidance of compensation schemes that link compensation to the volume or value of patient referrals; and
 - Documentation of the business purpose for the arrangement.
Is it commercially reasonable in the absence of referrals?



- Physician self-referral laws (like Stark) prohibit referrals for certain health care services by physicians to a person or entity with whom the physician has a financial relationship.
- Check whether each state has a self-referral prohibition.
 - Civil statutes but with strict liability
 - Often limited to physicians
 - Often limited to ancillary services (*e.g.*, imaging, lab)
 - Sometimes payor specific (*e.g.*, Medicaid, workers comp)
 - Cover compensation, ownership, or in-kind service remuneration, whether direct or indirect



- HIPAA provides a floor of privacy protection, but states are free to enact stronger privacy laws without HIPAA preemption.
- HIPAA prohibits contrary security laws but allows additional security provisions, including additional breach notification laws.



Corporate and Regulatory Considerations: Telehealth Contracting Patient Privacy Laws

- States often have heightened privacy protection for behavioral health, including substance use disorder, and sexual health.
- States often have separate breach reporting statutes.
- GDPR, California Consumer Privacy Act – signals for future of privacy and security rules?
- Make sure telehealth providers understand their privacy obligations, and that telehealth platform complies with applicable security laws.



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Privacy and security considerations when contracting with telehealth vendors:

- Business associate agreement
- Consider requiring cyber-insurance
- Vendor use of de-identified data – consider whether you want to give your data away for free
- Consider asking to see the vendor’s policies and procedures regarding protection of data
- “HIPAA-compliant”???



Corporate and Regulatory Considerations: Telehealth Contracting Corporate Practice of Medicine (NY)

New York State Education Department, Office of the Professions,
<http://www.op.nysed.gov/corp/>:

“Except where specifically authorized by law, a general business corporation may not:

- provide professional services to the public;
 - exercise any judgment over the delivery of professional services;
 - have employees who offer professional services to the public;
 - hold itself out as offering professional services; or
 - share profits or split fees with licensed professionals.”
- NY Attorney General – Aspen Dental settlement,
<https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-aspen-dental-management-bars-company-making>

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Corporate and Regulatory Considerations: Telehealth Contracting Corporate Practice of Medicine (Other States)

- States vary with respect to whether there is a corporate practice of medicine prohibition, and if so the strength of such prohibition
- Variation also exists with respect to which professions are subject to the prohibition



Applicability to telehealth:

- Most telehealth companies use a legal structure that permits access to the capital markets.
- Capital market access typically requires formation as a general corporation, sometimes a limited liability company, and typically precludes incorporation as a non-profit or professional corporation.
- Many states prohibit the practice of medicine and certain other health care professions by lay entities such as a general corporation or LLC.

- When considering contracting with a telehealth vendor, consider:
 - Will the vendor arrange for services by any professionals?
 - Through what legal entities can the profession practice?
 - Is there an employment v. independent contractor distinction?
 - What activities constitute the practice of the particular profession?

Telehealth Contracting – Reviewing the Vendor Agreement

- Contracting with companies to provide telehealth services can provide real value to patients from both a financial and health outcome perspective
- But such arrangements should be reviewed carefully – do not assume compliance with applicable laws
- Wise words from the OIG: “Just because your competitor is doing something doesn’t mean you can or should”
- Some areas to review closely:
 - Compensation
 - Business model/practice of medicine
 - Marketing
 - Privacy
 - Business terms



Telehealth Contracting – Reviewing the Vendor Agreement

- Typical starting point is a one-sided agreement in favor of vendor
 - Depending on leverage, the vendor expectation is often that terms will be negotiated
 - Implementation fees while the attorneys negotiate the agreement
- Specify what maintenance, training and support will be available, when and how it will be available, what it will cost and what terms and conditions will apply
- Different software errors should require different levels of response depending on severity. Ensure that critical issues are resolved immediately.



Telehealth Contracting – Reviewing the Vendor Agreement

- Adequate privacy and security protection for data
- Review termination provisions carefully!!
 - Is there a way out for cause? Without cause?
 - Is there transition assistance to help migrate to a new system or make other plans so as to not adversely affect patient care?
 - If terminated prior to end of term (e.g., for breach) how will payments or refunds be handled?
- Vendors often attempt to disclaim all warranties and liabilities and provide software “as is.” Providers will want broadest possible warranties.
- Reps, warranties, limitations on liability, disclaimers, indemnity and insurance all part of the risk equation and need to be considered together

Standard Software Representations and Warranties

- Software (and any hardware) has been produced in a workmanlike manner according to generally accepted industry standards and is free from defects in design, materials and workmanship
- Software will
 - not infringe on other parties' intellectual property rights,
 - be free of bugs and malicious code
 - be delivered in good condition
 - be serviced by appropriate personnel
 - have all required permits and comply with applicable laws and regulatory requirements

Specifications Representations and Warranties

- Vendors typically only offer a limited warranty that software will perform in accordance with specifications (which is often hedged by the words “materially” or “substantially”) or in accordance with documentation (which is provided after execution). Make sure that documentation adequately describes software functions and is consistent with pre-contract discussions or sales pitches
 - *Software (and any hardware) in all material respects conforms to the specifications agreed upon by the parties, which specifications shall include and incorporate by reference all written descriptions and representations presented by Licensor to Licensee in connection with the Software*

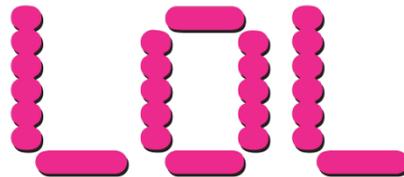


Non-Infringement Representations and Warranties

- Vendors typically will rep and warrant that the software will not infringe, misappropriate or otherwise violate any United States patent right
 - Try to expand to include non-infringement worldwide and for property, contractual, employment, copyright, trade secret, trademark or nondisclosure rights
 - Make vendor represent that the software is non-infringing even when integrated with other software
 - If any part of the Software contains Third Party Software, Licensor should represent that it has full power and authority and acquired all rights and licenses in the Third Party Software as necessary to embed it in the Software and/or sublicense it to Licensee
 - Make vendor represent that there is no pending litigation challenging or affecting Licensee's license grant

Limitations on Liability

- Limitations on liability (LOL) limit your recovery and may result in uncompensated damages
- LOLs often pegged to amounts paid for software and services
- LOLs should be fought because they bear no relationship to damages that might be caused by vendor
- Negotiate for either no cap on damages or cap that reflects the foreseeable damages from breach by vendor of license terms



Insurance and Indemnification

- Indemnification means nothing if vendor is insolvent
- Insurance provides a partial guarantee
- Vendor can add you as an additional insured
- Special policies for cyber-insurance can protect against security breaches



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