Telemedicine/Telehealth

It’s a complicated story

Presented by
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What is going on?

- Are we the Origination Site or the Distant Site?
- Why are we doing it?
  - Expanding the reach of services to new geographic areas, employer clinics, or patient couches?
  - Bringing expertise to rural and physician shortage areas?
  - Creating cost savings, increase quality or risk avoidance?
- Staying competitive with alternative care providers?
**Telehealth – Legal considerations**

- **Fraud and Abuse**
  - Stark (Where are the financial relationships? Do we have an exception?)
  - Anti-Kickback (watch for technology fee structures that could be viewed as incentivizing referrals in a particular direction)

- **Reimbursement**
  - Medicare telemedicine rules, Medicare Claims Processing Manual (know your MAC, the guidance varies)
  - Medicaid
  - Third Party Payor Agreement

- **Privacy**
  - HIPAA
  - Federal Trade Commission - unfair or deceptive acts or practices
  - Indiana Attorney General - Indiana Deceptive Consumer Sales Act

- **Licensure, Credentialing**
  - Delegation Credentialing
  - Licensure (certification needed for out-of-state providers)

- **Malpractice Insurance** (Are you covered?)

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**Telehealth/Telemedicine**

![Telehealth/Telemedicine Diagram]

*Diagram showing the flow of a telemedicine session.*
Telehealth – Documents

The documents:
- IT Services/License Agreement
  - Vendor terms of use
  - Vendor privacy policy
  - Vendor click through
- Clinical Services Provider
  - Clinical services agreement
  - Clinical services provider website
  - Privacy policy
  - Notice of privacy practices
  - Consent to treatment
  - HIPAA notice
- Hospital website
  - Terms of use
  - Privacy policy
  - Consent to treatment
  - HIPAA notice
- Joint Marketing Agreement
- Third Party Payor Agreement
- Medical Staff Bylaws
- Delegated Credentialing Agreement
- Medical Malpractice Policies
- Advanced Beneficiary Notice

Doctor on Demand Privacy Policy

We may also use your health information to:
- Comply with federal, state or local laws that require disclosure.
- Assist in public health activities such as tracking diseases or medical devices.
- Inform authorities to protect victims of abuse or neglect.
- Comply with federal and state health oversight activities such as fraud investigations.
- Respond to law enforcement officials or to judicial orders, subpoenas or other process.
- Inform coroners, medical examiners and funeral directors of information necessary for them to fulfill their duties.
- Facilitate organ and tissue donation or procurement.
- Conduct research following internal review protocols to ensure the balancing of privacy and research needs.
- Avert a serious threat to health or safety.
- Assist in specialized government functions such as national security, intelligence and protective services.
- Inform military and veteran authorities if you are an armed forces member (active or reserve).
- Inform a correctional institution if you are an inmate.
- Inform workers’ compensation carriers or your employer if you are injured at work.
- Recommend treatment alternatives.
- Tell you about health-related products and services....

https://www.doctorondemand.com/privacy-policies/site-privacy-policy
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• Contact you;
• Fulfill your requests for products, services, and information;
• **Send you information about additional clinical services or general wellness from us or on behalf of our affiliates and trusted third-party partners;**
• Analyze the use of the Services and user data to understand and improve the Services;
• Customize the content you see when you use the Services;
• Conduct research using your information, which may be subject to your separate written authorization;
• Prevent potentially prohibited or illegal activities and otherwise in accordance with our Terms of Use (which can be found at https://amwell.com/landing.htm); and
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• [https://www.americanwell.com/privacy-policy/](https://www.americanwell.com/privacy-policy/)

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Telehealth/Telemedicine

![Telehealth/Telemedicine Diagram](attachment:telehealth_diagram.png)
Understanding the Deal

* Allocating the Risk
  - Who bears the risk of a data breach?
    - Who is the Covered Entity?
  - Who is responsible for the Clinical Services?
    - Does the existing Malpractice Insurance cover Telehealth Services?
      - Geographic limits
      - Telehealth exclusion
    - What is the standard of care?
      - Is there a consensus of the medical staff on appropriate scope for telehealth diagnosis?
  - Who is responsible for obtaining sufficient patient consent?
  - Does the public appearance align with the contractual structure?
    - Joint marketing agreements
    - Platform and website design and branding

Delegated Credentialing

**Physicians:**

- Required to follow hospital medical staff bylaws for each hospital where physician is rendering services
- Be prepared to complete applications for each hospital
- Be prepared for cost of applications and multi-state licensure

**Hospitals:**

- Hospital is responsible for ensuring that the process meets the Medicare Conditions of Participation, Accreditation Standards and other pertinent legal requirements
- Obligation to ensure compliance with Medical Staff Bylaws – which may constitute a contract depending on jurisdiction
- Significant implications for failed credentialing
Medicare Conditions of Participation

- 42 CFR § 482.12 and § 482.22
- The governing body of the hospital whose patients are receiving telemedicine services may grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital or telemedicine entity
- Governing body must ensure:
  - Written agreement between hospitals
  - Distant site must be Medicare-participating hospital
  - Provider is privileged at distant site, which provides current list of Provider’s privileges
  - Provider holds a license issued or recognized by the state of originating site hospital
  - Originating site hospital conducts and shares internal review of provider’s performance with distant site hospital (at a minimum, all adverse events and complaints)
  - Governing body of the distant site hospital must meet (or distant site telemedicine entity must permit originating site to meet) the requirements of 42 CFR § 482.12 (a)(1) - (a)(7) regarding medical staff credentialing

The Joint Commission

- MS.13.01.01et seq; LD.04.03.09
- Joint Commission accredited originating site may only delegate to a distant site if the distant site is also Joint Commission accredited
- The originating site "retains responsibility for overseeing the safety and quality of services offered to its patients"
- The medical staff "recommends which clinical services are appropriately delivered...through this medium"
- The clinical services offered "are consistent with commonly accepted quality standards"
- Governing body ensures the written agreements satisfies the CoPs
Degree of Delegation – Options

<table>
<thead>
<tr>
<th>FULL CREDENTIALING</th>
<th>ADOPT DISTANT SITE RECOMMENDATION</th>
<th>HYBRID APPROACH</th>
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</table>
| • Go through the entire credentialing process same as any other medical staff member | • Medical Staff at the originating site may choose, for its recommendation, to rely fully on the credentialing determination made by the distant site  
• This is the default in most boilerplate contracts  
• Be careful regarding extent of "delegation" | • Originating site may rely upon credentialing information and/or recommendations from the distant site as part of its review process |

Delegated Credentialing – Considerations

• Carefully consider degree of intended delegation  
• Contemplate the mutual exchange of information  
  ─ Quality Review/OPPE and FPPE/Excluded Providers  
  ─ Differing peer review statutes and ability to share/protect peer review information  
  ─ Peer Review Sharing language/agreements  
• NPDB Queries and Background Checks  
• Insurance Requirements and Malpractice Acts  
• Disclosure/Comparison of Credentialing Standards  
• Disclosure/Comparison of Clinical Privileges (delineation vs. core)  
• Obligations and Standards of Subcontractors  
• Indemnification  
• Medical Staff Bylaws
Failed Credentialing – Implications

- Adverse implications for Quality of Care
- Compliance Concerns
- Professional Liability Concerns
  - Practitioner Liability
  - Negligent Credentialing
  - "Apparent" or "Ostensible" Agency
- Reimbursement

Medical Staff Bylaws – Considerations

- Compliance with the Medical Staff Bylaws is expected/required
- Medical Staff Bylaws may constitute an enforceable contract
- Bylaws should expressly contemplate delegated credentialing/telehealth services (and potential modification(s) to routine credentialing processes)
- Bylaws should additionally consider/address (as applicable):
  - Appropriate staff category
  - Administrative dismissal/resignation of membership and clinical privileges
Medical Staff Bylaws – Considerations

- Bylaws should additionally consider/address (as applicable), cont.
  - Telehealth Practitioner responsibilities and appropriate exemptions
    - Meeting Attendance
    - Meeting Participation and Manner of Participation (voting/nonvoting)
    - Medical Staff Dues
    - Immunization Requirements
    - Controlled Substance Registration (depending on nature of specialty/service)
    - Call/Coverage Obligations (depending on nature of specialty/service)
    - Consider flexibility to determine further exemptions

Professional Liability – Considerations

- Carefully consider respective roles/obligations
  - Method of communication
  - Timing of communication
  - Use/access to the medical record
  - Exclusions of coverage
- Establishing a practitioner/patient relationship
  - Consultation vs. "medical resource"
- Are telehealth consults recorded?
Please visit the Hall Render Blog at http://blogs.hallrender.com for more information on topics related to health care law.

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