

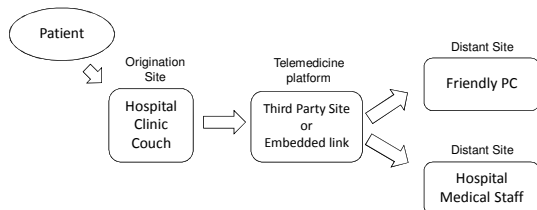
What is going on?

- 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?)

Telehealth/Telemedicine



Telehealth – Documents

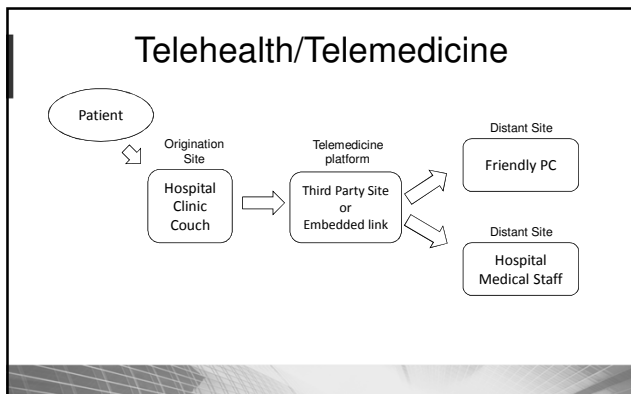
- The documents:
- IT Services/License Agreement
 - Vendor terms of use
 - Vendor privacy policy
 - Vendor click through
 - Clinical Services Provider
 - Clinical services agreement
 - Clinical services provider website
 - Privacy policy
 - Notice of privacy practices
 - Consent to treatment
 - HIPAA 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>

American Well - Privacy Policy

- We generally use the information we collect online to:
- Provide and improve the Services;
 - 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
 - For any other purposes disclosed to you at the time we collect your information or pursuant to your consent.
- <https://www.americanwell.com/privacy-policy/>



- ### 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
- | | |
|--|---|
| <p>Physicians:</p> <ul style="list-style-type: none"> • 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 | <p>Hospitals:</p> <ul style="list-style-type: none"> • 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.13.01.01 et 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

FULL CREDENTIALING

- Go through the entire credentialing process same as any other medical staff member

ADOPT DISTANT SITE RECOMMENDATION

- 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"

HYBRID APPROACH

- 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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