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 alterative 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

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- Comply with federal, state or local laws that require disclosure.
- Notify or advise a family member, legal guardian or other person involved in your care who is not present.
- Notify public health authorities about diseases or injuries.
- Prevent or control a seriousmun threat to health or safety.
- Respond to legal process.
- Conduct research using your information, which may be subject to your separate written authorization.
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- 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;
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- 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
      - 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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<tbody>
<tr>
<td>Go through the entire credentialing process same as any other medical staff member</td>
<td>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”</td>
<td>Originating site may rely upon credentialing information and/or recommendations from the distant site as part of its review process</td>
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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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