

GETTING PRACTICAL WITH **MEDICAL STAFF**

GOVERNANCE, CREDENTIALING & PEER REVIEW

Telemedicine Today

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Overview

- Essential terminology
- What we are seeing
- Law continues to follow technology
 - Federal law remains slow to catch up
 - State law more rapidly responding; however significant inter-state and intra-state variability
- Essential considerations for telemedicine arrangements



Essential Terminology

- **Originating Site** – Where the patient is located
- **Distant Site** – Where the telemedicine provider is located
- **Telemedicine/Telehealth**
 - Synchronous
 - Asynchronous/Store and Forward
 - Remote monitoring
- General treatment of "**telephone calls**" and "**questionnaires**"
 - "**Interactive**" questionnaires
- **NOTE**: Different jurisdictions, agencies, payors, etc. define these terms differently



What We Are Seeing...

- Direct-to-consumer telemedicine
 - Low acuity/web-based services
 - ESRD
 - Behavioral health
- Provider-to-provider telemedicine
 - Acute stroke management, pediatrics, etc.
- School-based telemedicine
- Employers
- Non-traditional providers



Mobile Health Applications

- 79% of Americans said they would be willing to use a wearable device to manage their health
- Currently over 318,000 health apps available on the top app stores worldwide, nearly double the number available in 2015 (more than 200 apps being added each day)
- Global mHealth app market had a projected value of \$28.32 billion for 2018; expected to reach \$102.35 billion by 2023
- Concerns regarding reliability/accuracy (mixed data)
- FDA and FTC struggling to keep pace



Complex Regulatory Framework

- Primary Considerations:
 - Professional Standards:
 - Can we use telemedicine? How can we use telemedicine?
 - Implications for: Licensure, Medical Consent, Prescriptions, Insurance, Fraud/Abuse, Privacy/Security, Credentialing, etc.
 - Reimbursement:
 - Can we get paid for telemedicine services?
 - Medicare and Medicaid requirements
 - Private Payor/Parity Provisions
- Significant variability among jurisdictions



Complex Regulatory Framework

- **Federal law:**
 - Medicare reimbursement remains limited
 - Authorized "originating sites" remain limited in scope (42 U.S.C.A. § 1395m (2019))
 - The following may qualify only if located in a defined rural setting:
 - Hospitals and CAHs
 - Physician Offices
 - RHCs and FQHCs
 - Skilled Nursing Facilities
 - Community Mental Health Centers
 - Recent exceptions for Renal Dialysis Centers, Acute Stroke Treatment and Substance Abuse Treatment



Complex Regulatory Framework

- **Federal law:**
 - Medicare reimbursement (continued)
 - Bipartisan Budget Act of 2018 (eased restrictions related to ESRD/telestroke)
 - SUPPORT for Patient and Communities Act – July 1, 2019 (eased restrictions for treatment of substance abuse disorders)
 - Mental Health Telemedicine Expansion Act (HR 1301) – introduced in February 2019
 - Creating Opportunities Now for Necessary and Effective Care Technologies for Health Act of 2019 ("CONNECT")
 - No federal "solution" to: definitions, licensure, parity, prescriptive authority (Ryan Haight Act), compliance, professional liability, etc.



Complex Regulatory Framework

- **Ryan Haight Online Pharmacy Consumer Protection Act (2008)**
 - Requires that that a practitioner perform at least one in-person medical examination of a patient prior to prescribing that patient a controlled substance
 - Allows use of telemedicine to prescribe controlled substances if the practitioner meets a "practice of telemedicine" exception
 - Exceptions:
 - Treatment in a hospital or clinic
 - Treatment in the physical presence of a practitioner
 - Indian Health Service or tribal organization
 - Public health emergency declared by the Secretary of Health and Human Services
 - Department of Veterans Affairs medical emergency
 - Other circumstances specified by regulation
 - Special DEA Registration



Complex Regulatory Framework

- **State law:**
 - Significant state activity in response:
 - State telemedicine acts addressing some/all of the following:
 - Permissible types of telemedicine/telehealth, licensure requirements, prescriptive authority, consent requirements, record requirements, other related standards
 - State Licensure Compacts (Physicians, RNs, NPs, PTs, Psychologists)
 - Medicaid expansion and Parity Provisions
 - High variability/inconsistency among states
 - The individual practitioner is expected to know and comply with these standards



Complex Regulatory Framework

- **State law (continued):**
 - High variability/inconsistency even within individual states
 - Telemedicine legislation vs. pre-existing law/guidance
 - Pre-existing law fails to contemplate telemedicine services
 - New legislation frequently fails to address all practice considerations
 - Professional conduct standards vs. Reimbursement standards
 - The definitions of telemedicine/telehealth routinely differ
 - The standards to practice telemedicine and get paid for such practice are routinely different

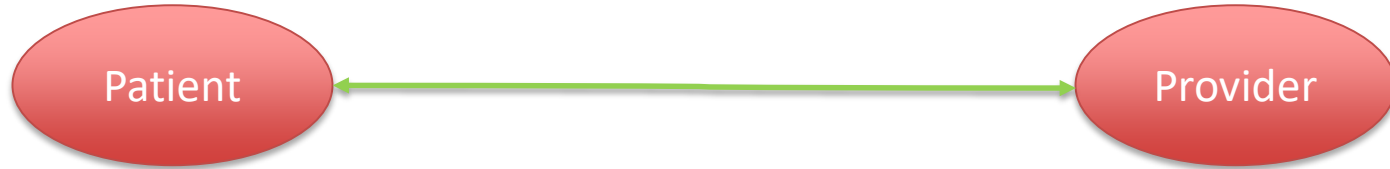


Telemedicine Arrangements

- Relative complexity
 - More parties generally involved
 - Technology/Software
 - Practitioner Coverage
 - More documents generally implicated
 - Consistency among documents/processes may be challenging
- Vendor reluctance to achieve consistency/compliance with health care specific requirements can be challenging



Telemedicine Arrangements



Service Contracts 
Privacy Documents 
Provider Agreements 



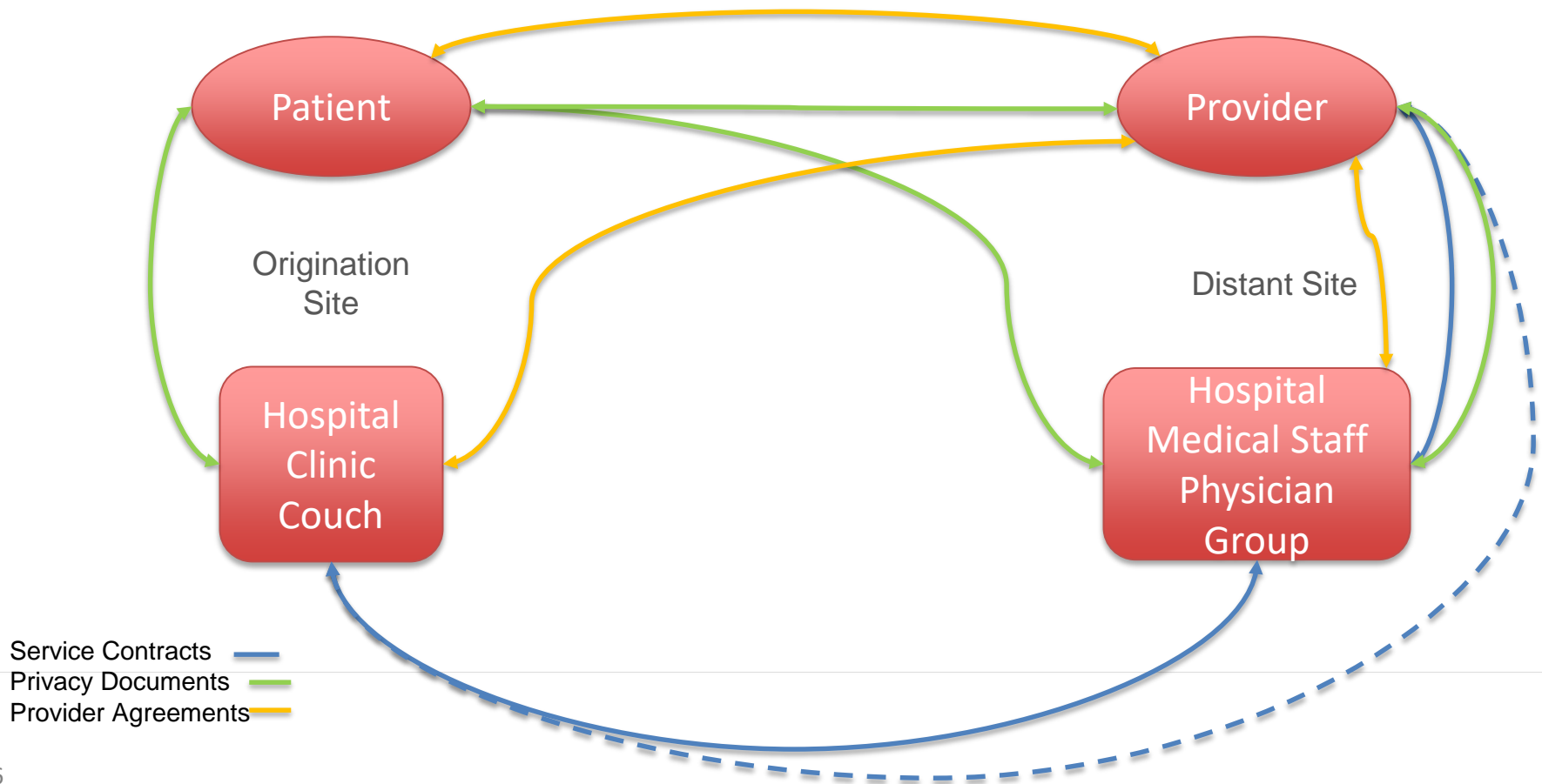
Telemedicine Arrangements



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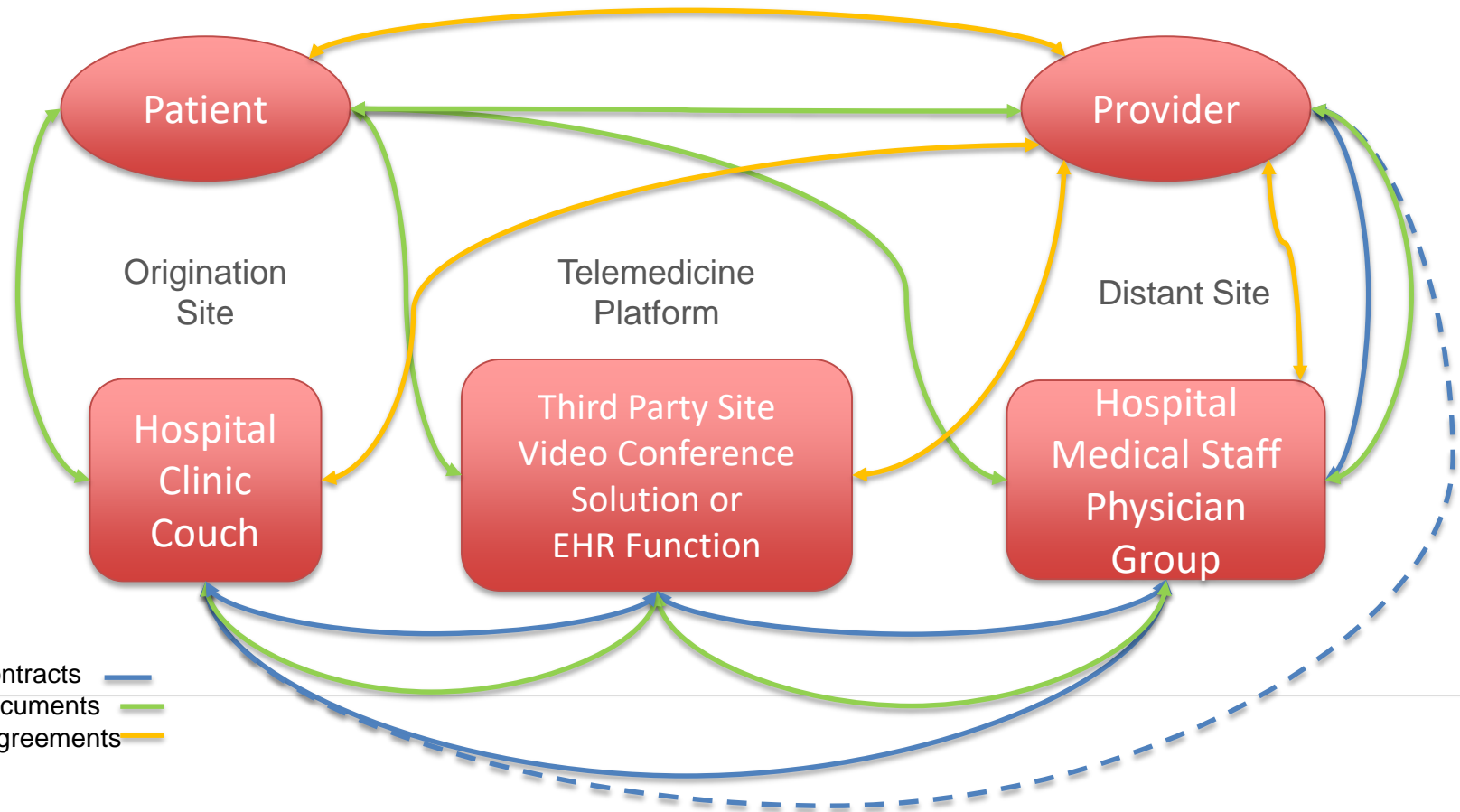
Telemedicine Arrangements



100



Telemedicine Arrangements



Documents Implicated

- 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
- IT Services/License Agreement
 - Vendor terms of use
 - Vendor privacy policy
 - Vendor click through
- Joint Marketing Agreement
- Third Party Payor Agreement
- Medical Staff Bylaws
- Delegated Credentialing Agreement
- Medical Malpractice Policies
- Advanced Beneficiary Notice



Privacy Policy – (Actual) Example

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; and
- For any other purposes disclosed to you at the time we collect your information or pursuant to your consent.



Telemedicine Arrangements

Initial Considerations:

- Are we the Originating Site or the Distant Site?
- Why are we providing the service?
 - Expanding the reach of services?
 - Creating cost savings, increase quality or risk avoidance?
 - Staying competitive with alternative care providers?
- Who is providing the service?
 - What providers are involved? Other individuals present?
 - Where are the services being rendered? Direct to consumer?



Additional Considerations

- Technology/Software
- Licensure/Scope of Practice
- Medical Consent/Recordkeeping
- Insurance/Allocation of Risk
- Prescribing
- Education and Workflow
- Reimbursement
- Delegated Credentialing



Technology/Software

- Will the infrastructure support the telemedicine service?
- Who is purchasing/providing telemedicine equipment?
 - Is equipment provided via grant awards?
 - Who is maintaining?
- Have you considered any compliance risk?
- Are there particular quality/resolution requirements?
- Has the technology been tested/approved?
- Are there licensing concerns?
- Have the appropriate personnel been trained?
- What happens when the technology doesn't work?



Licensure/Scope of Practice

- What originating sites/states are implicated?
- Which providers will be involved?
 - Are they licensed in the originating state?
 - Are they permitted to render services through telemedicine?
 - Are there relevant requirements regarding scope of practice, collaboration, supervision, etc.
- Is there an applicable exception/cross-border exception?
- Can you take advantage of an Interstate Licensure Compact?
- Are you creating a provider/patient relationship?
 - Consider risks attendant to Remote Second Opinions



Medical Consent/Recordkeeping

- Have you vetted the applicable state requirements for Medical Consent?
 - Are there specialty specific requirements (e.g., behavioral health)?
 - Are there applicable exceptions (e.g., **pediatrics/minors**)?
- How will you document medical consent?
- What PHI/Medical Records will be created?
- Who will have responsibility for the pertinent Medical Record? Who will have access?
- How will PHI be exchanged?
- How will PHI be stored? Where?



Insurance/Allocation of Risk

- Have you vetted the availability of professional liability insurance? Do you have sufficient coverage?
- Is there risk of "vicarious liability"?
- Does the public appearance align with the contractual structure?
- Who bears the risk of a data breach?
- Are there Indemnity, Force Majeure and/or Limitation of Liability provisions?
 - Should there be?
 - Should there be exceptions (e.g., data breach)?



Prescribing

- Will providers be prescribing medications via telemedicine?
 - State laws differ regarding when and what may be prescribed through telemedicine
 - States that have not specifically addressed prescribing typically default to standard requirements for in-person physical examination
 - Non-controlled legend drugs may possibly be prescribed (depends on state)
 - Controlled substances may generally not be prescribed (unless an applicable Federal law exception is met – Ryan Haight Act)
 - States may also provide for exceptions (but should be consistent with Federal law)



Education/Workflow

- Has the professional services workflow been specified?
 - Is the workflow compliant with law and the standard of care?
- Is the workflow realistic?
 - Turnaround/Response times
 - Method of communication
 - PHI provided
- Who and how will you educate the providers?
- Is there a contingency plan?
 - Technology/Software failures, breach, etc.
- Who will facilitate/assist to facilitate the encounter?
- Where will the patient be located? Privacy concerns?



Reimbursement

- Will this be a cash service/fee for service?
 - How will you establish Fair Market Value?
- Will you be seeking reimbursement from third party payors?
- Is reimbursement available?
 - Medicare (still limited by location, provider and nature of service)
 - Medicaid (expanding but still differs state to state)
 - Commercial (most states have enacted parity provisions)
- Who is seeking reimbursement?
 - Originating Site vs. Distant Site?
 - Employed Providers? Non-employed Providers?



Delegated Credentialing

- 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



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Delegated Credentialing

- Carefully consider permissible 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
- Insurance Requirements
- Disclosure/Comparison of Credentialing Standards
- Disclosure/Comparison of Clinical Privileges (delineation vs. core)
- Obligations and Standards of Subcontractors
- Indemnification
- Medical Staff Bylaws



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Please visit the Hall Render Blog at <https://www.hallrender.com/resources/blog/>
for more information on topics related to health care law.

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