Drafting Telemedicine Agreements: Legal Considerations for Hospitals and Physician Practice Groups
Navigating Regulatory Compliance and Corporate Practice of Medicine Issues, Negotiating Key Provisions

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Drafting Telemedicine Agreements:
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Physician Practice Groups

Navigating Regulatory Compliance and Corporate Practice of
Medicine Issues, Negotiating Key Provisions

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Outline of Presentation

I. Telemedicine Trends

II. Regulatory Framework for Telemedicine Agreements
   • Federal Regulations
   • State Requirements

III. Key Provisions - Looking Beyond the Legal Requirements
   • Risk Management and Quality Assurance
   • Business Considerations
   • Implementing Best Practices to Mitigate Risk
Telemedicine vs. Telehealth

CMS Definition:
• Telemedicine is the “provision of clinical services to patients by practitioners from a distance via electronic communications.”

American Telemedicine Association Definition:
• Telemedicine is the “use of medical information exchanged from one site to another via electronic communications to improve patients’ health status.
• Telehealth refers to a broader definition of remote health care that does not always involve clinical services.
Telemedicine vs. Telehealth

The Joint Commission Definition:

• **Telemedicine:** Use of medical information exchanged from one site to another via electronic communication to improve patients’ health status. Telemedicine is a subcategory of telehealth.

• **Telehealth:** Use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration.
Telemedicine vs. Telehealth

- **Telemedicine**: Delivery of specialty care at a distance via telecommunications using applications that provide direct patient care.

- **Telehealth**: Includes remote monitoring, telepharmacy, and non-clinical services, such as education programs, administration, and public health that can be provided remotely using communication technologies.
Telemedicine vs. Telehealth

Types of Telemedicine:

• **Non-simultaneous**: involve after-the-fact interpretation or assessment, such as teleradiology services

• **Simultaneous**: involve “real-time” interpretation or assessment, such as teleICU services

NOT Telemedicine:

• Informal consultations between practitioners

• Telephone conversation, e-mail/instant messaging conversation, or fax
Regulatory Framework for Drafting Telemedicine Agreements

• CMS’ Telemedicine Rule on Credentialing and Privileging
• HIPAA and HITECH Act
• Federal Fraud and Abuse Laws

*Note: Regulations dictate provisions that must be included in telemedicine agreements.*
CMS’ Telemedicine Rule

The Rule: PERMITS RELIANCE

- **Permits** a governing body of a hospital or critical access hospital (CAH) to rely on credentialing and privileging decisions made by distant-site hospitals or telemedicine entities when making privileging decisions for practitioners who provide telemedicine services, as long as certain conditions are met.

  (42 CFR §§ 482.12(a)(8)-(9); 485.616(c)(2),(4))

- Effective date of new rule was **July 5, 2011**.
Breaking Down CMS’ Telemedicine Rule

Definitions:

• **Distant-Site Hospital:** a Medicare-participating hospital that provides the practitioner who is providing the telemedicine services.

• **Distant-Site Telemedicine Entity:** can include a non-Medicare participating hospital or entity that provides contracted services in a manner that enables a hospital or a CAH using telemedicine services to meet all applicable CoPs. These entities often include teleradiology providers, telepathology providers, and ASCs.
Required Provisions Under Telemedicine Rule: Distant-Site Hospitals

To rely on a **distant-site hospital’s** credentialing and privileging decisions, the hospital or CAH **must have a written agreement** that establishes the following:

1. The distant-site hospital is a Medicare-participating hospital.
2. The distant-site practitioner is privileged at the distant-site hospital as evidenced by a current list of the practitioner’s privileges provided by the distant-site hospital.
3. The practitioner holds a license issued or recognized by the state in which the hospital or CAH whose patients are receiving telemedicine services is located.
4. The hospital that credentials and privileges the distant-site practitioner shares the practitioner’s performance review information with the distant-site hospital.

(42 CFR §§ 482.22(a)(3); 485.616(c)(2))
Required Provisions Under Telemedicine Rule: Distant-Site Telemedicine Entities

To rely on the credentialing and privileging decisions by a **distant-site telemedicine entity**, the hospital or CAH must have a **written agreement** that establishes the following:

1. The entity’s process and standards for assessing the qualifications of its practitioners at least meet those standards set forth in the CoPs.

2. The distant-site practitioner has the experience and expertise as represented by the distant-site telemedicine entity.

3. The practitioner holds a license issued or recognized by the state in which the hospital or CAH is located.

4. The hospital or CAH that credentials and privileges the distant-site practitioner shares the practitioner’s performance review information with the entity.

(42 CFR §§ 482.22(a)(4); 485.616(c)(4))
TJC Reaction To CMS’ Telemedicine Rule

The Joint Commission worked with CMS to align its telemedicine requirements for hospital accreditation.

- **Leadership Standard:**
  LD.04.03.09

- **Element of Performance 23:** Requires hospitals that use Joint Commission accreditation for deemed status purposes to have written agreements with distant sites.
Required Provisions: Drafting Agreements with Telemedicine Providers

• Hospitals are required, by law, to have detailed written agreements with a distant-site hospital or telemedicine entity to rely on the distant site’s credentialing and privileging decisions.

• Written agreements are required to include:
  - Specific responsibilities of telemedicine provider’s governing body or other responsible decision-makers
  - All provisions required by the CoPs

(42 CFR §§ 482.12(a)(8)-(9); 482.22(a)(3)-(4); 485.616(c))
Additional Considerations: Drafting Agreements with Telemedicine Providers

• Written agreements *should also* include:
  - Any additional standard with which a distant site’s credentialing and privileging process should comply
  - Adequate *representations and warranties* regarding the quality of services and credentialing/privileging processes provided by the distant site and any entity with which the distant site subcontracts

• **REMEMBER:** Physician Credentialing and Privileging Agreements often supplement and exist along with other agreements.
  - Provider Service Agreements
  - Equipment Agreements
Required Provisions Under Telemedicine Rule: Monitoring Performance

• Hospitals **are required** to monitor distant-site telemedicine practitioners.

• **THE RULE:** Hospitals using telemedicine services of distant-site practitioners must maintain evidence of an internal review of the distant-site practitioner’s performance of privileges and send information to the distant site for use in the periodic appraisal of the practitioner.

• The law requires, **at a minimum**, that the monitored and shared information include:
  1. All adverse events that result from telemedicine services provided by practitioner to patients, and
  2. All complaints the hospital has received about the practitioner

  (42 CFR § 482.22(a)(3)(iv), (a)(4)(iv))
Additional Considerations: Monitoring Performance of Telemedicine Providers

To Minimize Risk:

• Determine what additional information, if any, to collect as part of the monitoring process.

• Determine what information to share—no need to share too much.

• Only share and disclose information in a manner that preserves all peer review privileges under state law.

*Note: A telemedicine entity may not be a recognized peer review body under state law and thus not subject to any peer review privilege.*
Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Covered Entities: Health plans, health care clearinghouses, and any health care provider who transmits health information in electronic form.
Health Information Technology for Economic and Clinical Health (HITECH) Act

Providers billing for telemedicine services are responsible for:

- Complying with HIPAA and State-Specific Confidentiality and Privacy Rules for protection of protected health information (PHI).

- Ensuring policies and procedures are in place to prevent a breach in privacy or exposure of PHI (whether oral or recorded in any form or medium) to unauthorized persons.

Providers must maintain:

- Business Associate Agreements
- Patient Consent Forms
- Patient Rights for Telehealth Encounters
HITECH Act - Business Associates

**Business Associate:** Person or organization, other than a member of a covered entity's workforce, that performs functions or activities on behalf of, or provides services to, a covered entity that involve the use or disclosure of individually identifiable health information.
HITECH Act - Business Associate Services

- Legal
- Actuarial
- Financial services

- Accounting
- Consulting
- Data Aggregation

- Management
- Administrative
- Accreditation
Business Associate Agreements (BAAs)

• Since telemedicine consultations involve disclosure of PHI, a BAA between the remote site and the provider organization is recommended to properly protect the confidentiality of patient clinical information.

• The BAA may be incorporated into an affiliation agreement if the remote site is already affiliated with the provider organization.
Security Rule (45 CFR 164.3xx) Compliance - Risk Minimization

• Use of telemedicine services and technologies expands the number of people who have potential access to patients’ medical information.

• Develop policies and procedures that comply with federal and state privacy laws:
  - Administrative (45 CFR 164.308)
  - Physical (45 CFR 164.310)
  - Technical (45 CFR 164.312)

• Parties must understand how distant-site telemedicine practitioners will use, store, and maintain electronic health records (EHR) for patient care and liability purposes.
  - Role-Based Access Control (RBAC)
  - Data Encryption
  - De-identification of PHI
Fraud and Abuse Laws

Most fraud and abuse issues unique to telemedicine relate to the infrastructure, equipment, and support necessary to implement an effective telemedicine endeavor.

- Anti-Kickback
- STARK
- False Claims Act
- Civil Monetary Penalties
Anti-Kickback 42 U.S.C. § 1320a-7b(b)

Prohibits offering, paying, soliciting or receiving remuneration (anything of value) to induce or reward referrals or generate Federal Government health care business.

- **Equipment:** Telemedicine arrangements in which free telemedicine equipment or services are provided should be analyzed for possible remuneration risks and applicable Safe Harbors.

- **Note:** Physician access to hospital telemedicine equipment for remote consultations could implicate the anti-kickback statute unless the hospital takes necessary precautions to ensure the equipment and services are only used for the benefit of hospital patients, or any additional use is charged to the physician in accordance with the fair-market value (FMV) of access to the equipment.

- **Referrals:** Volume discounts and “per-click” arrangements in which an entity is reimbursed based on the number of Medicare referrals raise anti-kickback concerns.
Anti-Kickback Case Law

**United States v. Greber, 760 F.2d 68, 69-70 (3rd Cir. 1985)**

- Osteopathic physician was convicted of Medicare fraud for paying illegal remuneration to other physicians in return for referring patients for diagnostic services performed by his company, Cardio-Med, Inc.

- Cardio-Med provided cardiac monitoring, in which the data was stored in the device while the patient was wearing it and later uploaded to a computer (store-and-forward). The data was interpreted by the osteopathic physician at the Cardio-Med facility.

**United States v. Polin, 194 F.3d 863, 864 (7th Cir. 1999)**

- Physician was convicted of Medicare fraud for paying illegal remuneration to a cardiac devices sales representative in return for referring patients to the physician’s cardiac monitoring company, CVS.

- In the opinion, the judge explicitly addressed the telemedicine component of the arrangement and explained that the monitoring services could be performed by the monitoring physician while in direct contact with the patient or remotely using appropriate technology.
## Anti-Kickback Safe Harbors

<table>
<thead>
<tr>
<th>Investments in large publicly held health care companies and joint ventures</th>
<th>Space rental</th>
<th>Equipment rental</th>
<th>Personal services and management contracts</th>
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<tr>
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<td>Warranties</td>
<td>Discounts</td>
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<td>Waiver of beneficiary coinsurance and deductible amounts</td>
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<td>Obstetrical malpractice insurance subsidies</td>
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<tr>
<td>Cooperative hospital service organizations</td>
<td>Ambulatory surgical centers</td>
<td>Referral arrangements for specialty services</td>
<td>Price reductions offered to eligible managed care organizations</td>
</tr>
<tr>
<td>Price reductions offered by contractors with substantial financial risk to managed care organizations</td>
<td>Ambulance replenishing</td>
<td>Health centers</td>
<td>Electronic prescribing technology or training and Electronic health records software, IT or training</td>
</tr>
</tbody>
</table>

**NOTE:** Safe harbors that apply to telemedicine arrangements typically involve – **Space Rental; Equipment Rental; Personal Services and Management Contracts; Bona Fide Employees; Electronic Prescribing Technology or Training; and Electronic Health Records Software, IT or Training.**
Physician Self-Referral Law (STARK)
42 U.S.C. § 1395nn

• Stark Law prohibits a physician (or an immediate family member of such physician) from referring Medicare patients to entities providing designated health services if that physician, or the physician’s immediate family member, has a financial interest (ownership, compensation, or investment) in the entity.

• Practitioner must comply with Stark regulations if federal health care programs reimburse any of the referrals for designated health services.

• Telemedicine arrangements that involve free equipment or services, volume discounts, “per-click” payments, or advertisements on physician websites should be analyzed for possible self-referral risks and exceptions.
# STARK Exceptions

<table>
<thead>
<tr>
<th>Publicly traded securities</th>
<th>Mutual funds</th>
<th>Specific providers</th>
<th>Rental of office space</th>
<th>Rental of equipment</th>
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<tr>
<td>Bona fide employment relationships</td>
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<td>Certain group practice arrangements with hospitals</td>
<td>Payments by a physician</td>
<td>Charitable donations by a physician</td>
<td>Nonmonetary compensation</td>
<td>Fair market value compensation</td>
</tr>
<tr>
<td>Medical staff incidental benefits</td>
<td>Risk-sharing arrangements</td>
<td>Compliance training</td>
<td>Indirect compensation arrangements</td>
<td>Referral services</td>
</tr>
<tr>
<td>Obstetrical malpractice insurance subsidies</td>
<td>Professional courtesy</td>
<td>Retention payments in underserved areas</td>
<td>Community-wide health information systems</td>
<td>Electronic prescribing items and services</td>
</tr>
<tr>
<td>Electronic health records items and services</td>
<td>Physician services</td>
<td>In-office ancillary services</td>
<td>Prepaid health plan services</td>
<td>Academic medical center services</td>
</tr>
<tr>
<td>Implants (in ambulatory surgery centers)</td>
<td>Dialysis-related drugs (end-stage renal disease)</td>
<td>Preventive screening tests and immunizations</td>
<td>Post-cataract surgery eyeglasses and contact lenses</td>
<td>Intra-family rural referrals</td>
</tr>
</tbody>
</table>

**NOTE:** STARK exceptions that may apply to telemedicine arrangements involve: *Lease Arrangements* (rental of equipment or office space); *Bona Fide Employment Relationships*; *Personal Services Arrangements*; *Electronic Prescribing Arrangements*; and *Electronic Health Records Arrangements*. 

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Compliance with State Requirements

• Individual state requirements shape telemedicine practices.

• States have their own:
  ➢ Reimbursement Requirements
  ➢ Corporate Practice of Medicine Doctrine
  ➢ Licensing Laws and Requirements
  ➢ Consent Requirements
Medicare Reimbursement: Telemedicine - Telehealth

Medicare Reimbursement predicated on:

• **Nature of Service Rendered**: (Medicare Eligible Services / CPT or HCPCS Codes)

• **Location and Eligibility of Facility**: Service must be provided to a Medicare beneficiary in an eligible facility *(Originating Site)* located outside of a Metropolitan Statistical Area. 
  **NOTE**: No limitation on location of professional delivering the medical service *(Referring Site).*

• **Eligibility of Providers Rendering Service**: Physician or practitioner must be licensed under state law to provide the telemedicine service, and must be one of the following practitioners:
  - Physician, Nurse Practitioner, Physician Assistant, Nurse-Midwife, Clinical Nurse Specialist, Clinical Psychologist, Clinical Social Worker, or Registered Dietitian/Nutrition Professional.

• **Claim Submission**: 
  - Distant site physician/practitioner will bill CPT Code + GT modifier (“interactive audio and video telecommunications system”).
  - Facility payment, physicians/practitioners will bill HCPCS code “Q3014, telehealth originating site facility fee,” short description “telehealth facility fee.”
State Medicaid Requirements and Private Payor Reimbursement

• State Medicaid programs and private payors have developed a wide range of reimbursement policies, from complete denial to full reimbursement of any covered medical service provided through telemedicine.

• Carefully scrutinize state Medicaid reimbursement policies, state health insurance regulations, and private payor contract requirements for licensing or accreditation standards that pertain expressly to telemedicine services.

NOTE: Some states such as California, Colorado, and Kentucky require a range of heightened informed consent, quality of care, and privacy requirements for Medicaid reimbursement of telemedicine services.
Corporate Practice of Medicine Doctrine

• **Prohibits** the practice of medicine through a **business corporation** or a **limited liability corporation** or **partnership** that is not wholly owned by professionals, licensed in the jurisdiction, where the entity is providing telemedicine services.

• **Penalties:**
  - Physicians may face professional discipline and other penalties.
  - Institutions contracting for telemedicine services may have exposure under state statute, regulation or case law.

> STEPS TO TAKE <

(1) Confirm that the jurisdiction in which the telemedicine services are to be rendered allows the provision of professional medical services through the type of entity utilized. (*Example: LLC, PC*)

(2) If entity is authorized, confirm that the entity is qualified to do business in the jurisdiction (as a foreign domiciled entity, if necessary).

(3) Ensure that the owners of the entity are properly licensed in all jurisdictions in which the entity does business.
State Licensure Requirements

• Significant Barrier: Most states require physicians engaging in telemedicine to be licensed in the state where the patient is located.
  ❖ As of June 2013, TEN state medical boards authorized a special license or certificate to provide telemedicine services across state lines.
  ❖ Limited consultation exceptions for practice by out-of-state physicians.

• **NOTE:** Continuing efforts to reduce barrier.
  ❖ Monitor state medical board guidance.
  ❖ FSMB-Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine
State Consent Requirements

• Is patient consent required when providing telemedicine services?
  ➢ Federal Law: Not specified
  ➢ State Law: Varies from state to state.

• What level of consent is needed?
  ➢ Verbal consent documented in patient’s medical record
  ➢ Informed consent
  ➢ Notice regarding telemedicine services

• Who is responsible for obtaining consent?
  ➢ Treating health care provider
  ➢ Failure to comply may constitute unprofessional conduct
Key Provisions - Looking Beyond the Legal Requirements

• Risk Management and Quality Assurance
• Business Considerations
• Implementing Best Practices to Mitigate Risks
Risk Management: Provision of Services

Identify and Understand:

- Scope and purpose of services.
- Who will be involved in providing the services, including any subcontractors.
- How services will be provided and in what time frame they must be provided.
- Expectations of regulatory compliance when providing services.
- What other written agreements are needed or already exist.
Risk Management: Equipment and Technology

• In contracts for **telemedicine services**, identify:
  - Equipment needed to provide telemedicine services.
  - Who is responsible for providing and maintaining the equipment.
  - What staff and technical support is needed to service and maintain the equipment.
  - Who is authorized to use telemedicine technologies.
  - How patient interaction/consultation/visit will continue if there is a technology problem, how to respond to emergencies.

• In contracts with **telemedicine technology vendors**:  
  - Protect against liability for equipment failure.
  - Ensure appropriate secure communication channels are in place.
  - Ensure access to continued support services, technology updates.
  - Have vendor represent and warrant technology’s compliance with regulatory requirements.
Risk Management: Education and Training

• **Identify:**
  - What education and training is needed to use telemedicine technology and provide telemedicine services.
  - Cost of training and who will be responsible for training.
  - How education, training, and competence will be assessed.

• **Practical Considerations:**
  - Educate/Train all administrators, employees, and medical staff members regarding appropriate use of telemedicine technologies and distant-site telemedicine practitioners.
  - Develop a quality improvement process to identify needed improvements and react to changes.
Risk Management: Qualifications of Physicians

Sample Contract Language in Provider Services Agreement:

Qualifications. Telemedicine entity represents and warrants that each physician who provides Services to Hospital shall comply with all applicable Medical Staff qualification requirements set forth in Hospital medical staff bylaws, rules, regulations, guidelines, and policies and shall maintain, throughout the term of the agreement:

- Current, unrestricted license to practice in the state;
- Membership in good standing in the telemedicine entity;
- Membership in good standing with unrestricted clinical privileges appropriate for providing Services, at affiliated Hospital;
- Current, unrestricted federal and state controlled substances registration;
- Medicare and Medicaid provider numbers; and
- All other licenses and certificates that may be lawfully required.
Risk Management: Qualifications of Physicians

Malpractice Coverage Check List

✓ Claims Made or Occurrence
✓ Is the coverage within respective limits? *Example:* $1,000,000 per occurrence and $3,000,000 in aggregate. *(Check State-Specific Requirements)*
✓ Does the professional liability insurance policy afford coverage for telemedicine service? Obtain written assurance from insurance carrier that the policy covers telemedicine malpractice.
✓ If the physician will be providing services across state lines, ensure that the malpractice liability extends coverage to multiple states

**TIP:** Each party should provide to the other party a Certificate of Insurance evidencing coverage, and should promptly notify the other party following any modification of coverage.
Risk Management: Standards of Care

• **Standard of Care:** (State-Specific) Ordinarily, the standard of care is the same whether the patient is seen in-person or through telemedicine, or other methods of electronically-enabled health care.

• **Building Blocks of Protocol**
  - Create protocol based on policies and procedures unique to your organization.
  - State the rationale for the protocol.
  - Identify the individuals affected by the protocol.
  - Describe procedure for compliance.
  - Identify preferred behaviors.
  - Identify contingent behaviors *(Example: Computers are off-line).*
  - List oversight responsibilities.
  - Identify consequences for non-compliance.
Risk Management: Quality Measures

- Review Existing Telehealth Protocol
- Identify Threats and Vulnerabilities
- Mitigate Risk
- Assess Risk

Quality Measures
- Images
- Data
- Reports

Monitor Results
Business Considerations: Physician Scheduling

• By Agreement of the Parties
• List of Scheduled Physicians (Attached as Exhibit to Agreement)
• Procedures for Modification of Listed Physicians

1. Notice of Revised Schedule – Telemedicine Entity shall provide Hospital with revised Schedule indicating the name of any new Physician.

2. Action by Hospital to Revised Schedule – Hospital to sign and fax updated Schedule if “new” physician added. If the only changes were removals, Telemedicine Entity may remove Physician(s) without waiting for signed Schedule to be returned.

3. Action to Initiate Removal of Physician - If Hospital no longer wishes to receive telemedicine consultative services from a Physician, for reasons not requiring a hearing, Hospital shall request Telemedicine Entity remove the Physician from the Schedule.
Business Considerations: Term and Termination

Sample Contract Language:

Term: This Agreement will commence as of the Effective Date and continue for a period of one (1) year (the "Initial Term"). Thereafter, with mutual consent of the parties, the Agreement will automatically renew for subsequent terms of one (1) year.

Termination:

- By Agreement
- Without Cause
- With Cause
- Cure Period (30 Days)
Business Considerations: Restrictive Covenants

Consult State Law

Common Covenants:
- Non-Compete - May not participate in the “Same” or “Similar” Medical Practice
- Non-Solicitation - May not “Contact” or “Solicit” Patients or Employees of the Practice

Reasonableness:
- Time
- Place
- Geographic Scope

Liquidated Damages Provision: (Example: $225,000)
- Facility/Telemedicine Provider
- Telemedicine Provider/Physician
Business Considerations: Confidentiality of Proprietary Information

Sample Contract Language:

• Parties each acknowledge and agree that in the course of performance under this Agreement, it may have access to certain information proprietary to the other party, including but not limited to trade secrets, policies, procedures, operating manuals, utilization and quality assurance programs, software, marketing techniques, contractual arrangements, patient names, patient lists, price lists, pricing policies, and financial information (collectively "Proprietary Information").

• Parties will maintain the confidentiality of all Proprietary Information belonging to the other party and will not divulge such information to any third parties, except as otherwise provided for under this Agreement and under law.
Implementing Best Practices to Mitigate Risks

• **Within** the Written Agreements:
  
  - Address greater oversight concerns that arise when contracting with a distant-site telemedicine entity rather than a licensed, distant-site hospital.
  - Require additional assurances if a distant site **subcontracts** with a telemedicine entity.
  - Avoid relying solely on representations and warranties.
  - Include tight, protective **indemnification** and **risk-sharing provisions**.
  - Require distant-site telemedicine entities have sufficient **liability insurance**.
Implementing Best Practices To Mitigate Risks

• *In addition to* the Written Agreements:
  
   Communicate regularly with distant-site hospitals and telemedicine entities and other practitioners involved in patient’s care.

   Be knowledgeable of the roles and responsibilities of all parties involved in the delivery of health care services.

   Understand the purposes and boundaries of all technologies or potential technologies.

   Regularly monitor state and federal laws and regulatory guidance.
Summary of Key Provisions

- Credentialing and Privileging, Peer Review
- Equipment, Use of Space
- Provision of Services, Responsibilities of the Parties
- Subcontractor Arrangements
- Provider Qualifications, Liability Insurance, Medical Staff Membership and Clinical Privileges
- Medical Records, Confidentiality, Maintenance, Access to Records
- No Referrals, Billing, and Collections
- Term and Termination
- Representations and Warranties
- Indemnification
Drafting Telemedicine Agreements: Legal Considerations for Hospitals and Physician Practice Groups

Navigating Regulatory Compliance and Corporate Practice of Medicine Issues, Negotiating Key Provisions

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