

Telemedicine: A Legal Overview and Analysis

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Telemedicine Definition

- Practice of health care delivery, diagnosis, consultation, treatment, transfer of medical data and education.
- Using interactive audio, video or data communications.
- With a patient at a location remote from the provider.
- Does not include telephone or facsimile communication.

Informed Consent

- The health care provider who has ultimate authority over the care of the patient receive the patient's informed consent before delivering care through telemedicine (e.g., California, Kentucky, Oklahoma).
- Elements:
 - Description of telemedicine consult
 - Associated risks, consequences and benefits (transmission interruption, equipment delays, potential access to medical data)
 - Must assure all confidentiality protections apply
 - Dissemination of images or information shall not occur without patient's consent
 - Patients may withdraw consent for telemedicine at any time without affecting the right to future care of treatment

The Medical Record

- Assure that all information transmitted for the consultation be made part of the medical record (Required by some states, e.g., California, Colorado).
- Develop retention and storage policy for telemedicine encounters.

Licensing Requirements

- About 29 states have adopted statutes addressing licensing requirements for out of state physicians.
- Most states exempt telepathology and teleradiology interpreting services from licensing requirements, but not all (e.g., Connecticut, New Hampshire).

License Requirements

- General Models:
 - No Exception: full license required (e.g., Louisiana, Massachusetts, Michigan, South Carolina)
 - May only provide 2nd Opinion (e.g., Illinois, Tennessee)
 - May provide consultations only - no ultimate authority over the patient (e.g., California, Florida, New York, Pennsylvania)
 - May provide all services, but only on an infrequent basis (e.g., Alabama, Minnesota)
 - Full Exception (e.g., Washington, New Jersey)

License Requirements: Other Health Care Providers

- Emerging area for telehealth programs
- National Licensing Exam for Pharmacists
 - Since 2004, single national pharmacy exam administered by NABP
 - Ability to transfer license from state to state
 - Each state may have specific requirements, e.g., registration, jurisprudence exam

License Requirements: Other Health Care Providers

- Nursing Licensure Compact
 - Interstate Compact adopted by 24 states
 - Mutual recognition model: practice across state lines is allowed, whether physical or electronic, unless the nurse is under discipline or a monitoring agreement that restricts practice across state lines
 - Does not apply to advance practice nurses

Professional Liability Insurance

- Is telemedicine covered?
- Any limitation as to location or region?
- Private Insurers
 - Specific questions on telemedicine: location, frequency, type
 - Requires that physician be licensed in the state receiving services
 - Requires prior written approval from insurer

Malpractice Liability Exposure

- Some states have statutorily defined the location of the telemedicine act as the physical location of the patient (e.g., Nevada).
- Some states laws mandate that providing telemedicine submits the practitioner to the jurisdiction of that state e.g., Montana, Illinois).
- Provider is exposing him/herself to the jurisdiction and venue where the injury occurred.

Joint Commission

- Joint Commission developed telemedicine standards, effective 1/01/01 and revised 1/01/04.
- Applies to hospitals and ambulatory care facilities.
 - Practitioners who treat patients via telemedicine must be credentialed with the organization that receives the telemedicine service
 - Medical staff of the receiving facility determines which telemedicine services are appropriate

Joint Commission

- Standards do not apply to telemedicine providers adhering to a consultative model (e.g. specialists do not diagnosis, treat or prescribe), or “interpretive” services (radiology & pathology).
- Standards do apply to “treating” physicians-- those who diagnose or otherwise assume a higher level of patient care.
- Providers providing direct care (e.g. medical director for a PICU giving nurse orders) should be fully credentialed.
- Joint Commission standard equipment management and medical record management standards also apply to telemedicine.

CMS Requirements for Hospital Medical Staff Privileging

- The hospital's Governing Body must ensure that all practitioners who provide a medical level of care and/or conduct surgical procedures in the hospital are individually evaluated by its Medical Staff and that those practitioners possess current qualifications and demonstrated competencies for the privileges granted.

HIPAA and Issues Unique to Telemedicine

- Distribution of the *Notice of Privacy Practice* to patient, if the health care provider is not a member of the patient site workforce.
- HIPAA privacy training/education if the health care provider is a member of the patient site workforce.
- Business associate agreements with technical providers (non-covered entities) who assist with the delivery of healthcare by telemedicine.

Anti-Kickback Statutes

- Federal law makes it a crime to offer, solicit, pay or receive any remuneration intended to induce, or is in return for, the referral of patients or the ordering of items or services reimbursable by any federal health care program.
- Remuneration is anything of value.
- Law is violated if only “one purpose” of an arrangement is to induce referrals.
- State law often has similar prohibitions; may be more broad, e.g., all payers.
- Penalties can include fines, imprisonment and exclusion from the Medicare program.

Potential Fraud and Abuse Issues

- Provision of free or below cost equipment
- Physician compensation arrangements
- Use of space / lease arrangements
- Provision of computer or other technical services

STARK

- Federal law prohibits physicians from referring Medicare beneficiaries to an entity which the physician has a financial interest for designated health services (DHS) reimbursable by Medicare.
- Statute is more limited:
 - Only applies to physicians
 - Only for DHS: clinical laboratory services, radiology, PT, OT, speech, radiation therapy, DME, parenteral and enteral nutrients, prosthetics, orthotics, home health, outpatient drugs, inpatient or outpatient services
- Penalties more severe: strict liability.

Potential STARK issues

- Favorable medical director agreements
- Investment interest in certain telemedicine-related companies/services

Checklist

- Review your policies and processes:
 - Medical records management (consent, transmission of records from referring provider, retention)
 - Privileging requirements
 - License issues
 - Professional liability coverage
 - HIPAA privacy compliance (NPP, BA agreements)
 - Contracts and payment arrangements