Telemedicine and Telehealth

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Agenda

• What is Telemedicine/Telehealth?
• Business Models
• Legal and Regulatory Issues
• Key Considerations in Telemedicine Agreements
• Recent AMA Guidelines and Federation of State Medical Boards Compact
• Questions
What is Telehealth?

• “The use of telecommunications and information technology to provide access to health diagnosis, assessment, intervention, consultation, supervision and information across a distance.” (CMS)
  – Includes telephones, fax machines, e-mail systems, and remote patient monitoring devices used to collect and transmit patient data for monitoring and interpretation.

• “Telemedicine” is included within this definition.
What is Telemedicine?

• “The provision of clinical services to patients by practitioners from a distance via electronic communications.” (CMS)
  – Distant-site practitioner provides services to patient simultaneously (e.g., teleICU) or non-simultaneously (e.g., teleradiology).

• “The use of medical information exchanged from one site to another via electronic communication to improve patient health.” (Joint Commission)
What is Telemedicine?

• Informal consults between practitioners at different locations are NOT telemedicine.
  – Distant-site practitioner is providing an opinion to attending practitioner, not providing services directly to the patient.
  – Consider:
    • Patient present during consult?
    • Distant-site practitioner interacting with patient?
    • Which practitioner is ordering the treatment?
Business Models

• Retail Clinics
• Virtual Medicine
• Traditional telemedicine

• Evolving Regulatory Landscape
• Common Legal Issues
Legal and Regulatory Issues

- Licensing and Scope of Practice
- Supervision/Collaboration Requirements
- Prescriptive Authority
- Federal and State Privacy Laws
- Reimbursement
- Corporate Practice of Medicine
- Malpractice Risk
Licensure

• Practitioners must meet licensing requirements in the state where the patient is located.
• Key issue in any telemedicine arrangement.
• State laws regarding telemedicine vary:
  – Some state licensing laws directly address telemedicine and explicitly define the practice of telemedicine.
  – Some states laws indirectly address telemedicine by defining the practice of medicine to include diagnosing or recommending treatment through electronic means.
  – Some states are silent.
Licensure

• Some states require full licensure of practitioners providing telehealth services to patients in state.
  – “Active” or in-state practice requirements

• Some states have special telemedicine licenses (e.g., MN, MT).

• State Licensure Exceptions:
  – Physician-to-physician consults
  – “Infrequent” or “occasional” consultations (e.g., fewer than 10 consults per year)
Scope of Practice

• Use of non-physician practitioners increasing
  – In telemedicine context, this raises issues regarding scope of practice, supervision, and prescriptive authority.

• Other considerations:
  – Written collaborative agreement requirements
  – Protocols

• Nurse Licensure Compact
Physician Supervision

• Levels of Supervision:
  – General supervision: Procedure must be furnished under physician’s direction and control, but physician’s presence not required.
  – Direct supervision: Physician must be present in office suite and immediately available.
  – Personal supervision: Physician must be in attendance in room during procedure.
Physician Supervision

• Direct supervision/on-site requirements can significantly impact telemedicine arrangements.

• Is remote supervision acceptable?
  – Non-physician practitioner and patient in same location, but supervising physician off-site.

• Must review state requirements
  – Physician/non-physician practitioner practice ratios
Prescriptive Authority

• Issues surrounding prescribing medication electronically in connection with telehealth encounters.

• Permissibility of remote prescribing varies significantly across states
  – State pharmacy statutes and regulations
  – Licensing board policy
  – Medicaid reimbursement policies
Prescriptive Authority

• State prescribing requirements that create biggest hurdles in telemedicine context:
  – Face-to-face encounter
  – Physical examination
  – Existing physician-patient relationship
  – Controlled substances

• Efforts to clarify requirements/change law and accommodate online consultations.
Privacy and Security

• HIPAA’s Applicability
  – Covered Entities
  – Business Associates

• Protected Health Information
  – Individually identifiable information (written, electronic, or oral) created or received by a provider;
  – Relating to an individual’s health, provision of health care to an individual, or payment for health care;
  – That identifies the individual or provides a reasonable basis to identify the individual.
Privacy and Security

• HIPAA Security Rule
  – Requires implementation of administrative, physical, and technical safeguards to protect electronic PHI.
  – Covered entities and business associates must:
    • Ensure the confidentiality, integrity and availability of ePHI that it creates, receives, maintains or transmits;
    • Protect against reasonably anticipated threats or hazards to the security or integrity of ePHI;
    • Protect against impermissible uses or disclosures; and
    • Ensure compliance by all workforce members.
Privacy and Security

• Important to consider the following issues:
  – Organization size, complexity, and capabilities;
  – Organization’s technical infrastructure, hardware, and software security capabilities;
  – Costs of security measures; and
  – Probability and criticality of potential risks to ePHI.

• Examples:
  – Encryption
  – User authentication
  – Secure network
Privacy and Security

• Must also consider state laws that apply to telemedicine arrangements.
• Applicable state laws may be more stringent than HIPAA.
• Some states have recordkeeping and privacy laws relating specifically to telehealth encounters.
Credentialing and Privileging

• In 2011, CMS issued rule changing hospital Conditions of Participation to permit hospitals to rely upon credentialing and privileging decisions of a distant-site hospital for telehealth practitioners (42 CFR 482.12; 482.22).
  – Distant site can be either Medicare-participating hospital or telemedicine entity (e.g., teleradiology, teleICU, teleneurology).
  – “Originating site” is the location of the eligible Medicare beneficiary at time telehealth service occurs.
Credentialing and Privileging

Hospitals using this option must ensure:

• Distant-site hospital is Medicare-participating hospital;
• Distant-site practitioner is privileged at distant-site hospital;
• Originating-site hospital has an internal review of distant-site practitioner’s performance and provides this information to distant-site hospital;
Credentialing and Privileging

Hospitals using this option must ensure (cont’d):

• Distant-site hospital provides a current list of practitioner’s privileges;
• Distant-site practitioner holds a license issued or recognized by state of originating-site hospital; and
• Information sent from originating-site to distant site must include all adverse events and complaints from telemedicine services provided by distant-site practitioner to originating-site hospital’s patients.
Credentialing and Privileging

• Written agreement required between originating-site hospital and distant-site hospital/entity.
• Agreement must specify that:
  – Distant-site hospital is furnishing services in a manner allowing originating-site hospital to comply with applicable CoPs and standards.
  – Distant-site telemedicine entity is a contractor of services to originating-site hospital and entity provides services that comply with applicable CoPs and standards for contracted services.
Telemedicine Agreements

Key Considerations:

• Clearly identify all parties involved.
  – Are any subcontractors involved?
  – What types of practitioners will be involved?
  – What types of facilities will be involved?
  – In what states will parties and patients be located?

• Will the arrangement involve remote prescribing?
Telemedicine Agreements

Key Considerations (cont’d):

• Are there any applicable state telemedicine requirements (e.g., recordkeeping)?
• What written agreements are needed?
• What equipment is needed and who is providing/maintaining the equipment?
  – Consider fraud and abuse laws
• Identify payors and reimbursement issues.
Reimbursement

• Employers and Individuals
• Private/Commercial Payors
• Government Payors
  – Medicare
  – Medicaid
  – Other
States and Private Payors

• Wide range of telemedicine reimbursement policies among state Medicaid and private payors.
  – 46 states and D.C. offer some form of Medicaid reimbursement for telemedicine services.
  – 9 states pay for store-and-forward technology.
  – 14 states pay for remote patient monitoring.
  – 19 states and D.C. mandate that private payers cover telemedicine services.
State Coverage of Telemedicine

Source: National Conference of State Legislatures
Medicare Reimbursement

• Medicare reimbursement for services delivered via telemedicine or telehealth covers:
  – Remote patient face-to-face services seen via live video conferencing.
  – Non face-to-face services conducted through live video conferencing or via asynchronous, store and forward telecommunication services.
Remote Face-To-Face Services

• Medicare reimbursement is available only if certain requirements are met regarding:
  – Geographic location of originating site,
  – Type of services provided,
  – Type of institution delivering the services, and
  – Type of health provider.
Remote Face-To-Face Services

• Originating site must be:
  – Rural Health Professional Shortage Area (HPSA);
  – County that is not a Metropolitan Statistical Area (MSA); or
  – Approved demonstration project.

• No limitation on location of distant-site health professional delivering the service.
Remote Face-To-Face Services

• New for 2014: “Rural HPSA” is a HPSA located in a rural census tract as determined by Office of Rural Health Policy.
• Based on status of HPSA as of December 31 of prior calendar year.
• CMS website tool:
Remote Face-To-Face Services

- Eligible Originating Sites:
  - Office of a physician or practitioner
  - Hospital
  - Critical access hospital
  - Rural health clinic
  - Federally qualified health center
  - Skilled nursing facility
  - Hospital-based dialysis center
  - Community mental health center
Remote Face-To-Face Services

• **Eligible Distant Site Practitioners**
  – Physician;
  – Nurse practitioner;
  – Physician assistant;
  – Nurse midwife;
  – Clinical nurse specialist;
  – Clinical psychologist,
  – Clinical social worker; and
  – Registered dietitian or nutrition professional.
Remote Face-To-Face Services

• **Eligible Medical Services**
  – Consultations, office visits, individual psychotherapy and pharmacologic management delivered via a telecommunications system.
  – Interactive audio and video telecommunications system must be used that permits real-time communication between distant site practitioner and patient.
  – Fee schedule includes list of Medicare telehealth covered services by CPT or HCPCS code.
Remote Face-To-Face Services

- **Eligible Medical Services**
  - Reimbursement to professional delivering service via telecommunication is same as current fee schedule amount.
  - Submit CPT code for professional services with GT modifier ("via interactive audio and video telecommunications system").
  - Originating site is eligible to receive a facility fee.
  - Q3014 ("telehealth originating site facility fee")
Remote Face-To-Face Services

• CPT codes 99495 and 99496 (Transitional Care Management Services) recently added as telehealth-covered services.

• Limit of one telehealth visit every 3 days for subsequent hospital care services.

• Limit of one telehealth subsequent nursing facility care service every 30 days.
Remote Non-Face-to-Face Services

• Services delivered via telecommunications may be covered as physician services.
  – “A service may be considered to be a physician’s service where the physician either examines the patient in person or is able to visualize some aspect of the patient’s condition without the interposition of a third person’s judgment.” Medicare Benefit Policy Manual, Ch. 15, § 30.
  – Direct visualization is possible by means of x-rays, electrocardiogram, tissue samples, etc.
Corporate Practice of Medicine

- Corporate practice of medicine ("CPM") doctrine prohibits corporations from employing medical professionals or owning/controlling medical practices.
- Intended to prevent lay persons from exerting control or influence over physician medical decision-making.
- CPM prohibition has been widely criticized.
Corporate Practice of Medicine

• Based on state statute, case law, attorney general opinions, board policies, etc.
• Enforcement of CPM prohibition varies
  – Some states are more active (e.g., CA, NY)
• Exceptions vary by state
  – Hospitals
  – Entities owned solely by licensed professionals
Corporate Practice of Medicine

• Potential ramifications of CPM violations:
  – Refusal to pay claims
  – Injunction against continued operation of clinic
  – Criminal prosecution for engaging in unauthorized practice of medicine
  – Entire arrangement could be declared void
  – Violation of fraud and abuse laws (e.g., False Claims Act)
  – Loss of “private practice”, “physician office” and similar exceptions from state licensing requirements (CON, lab license, etc.)
Corporate Practice of Medicine

• Potential solutions to CPM problem:
  – If state CPM prohibition applies to telemedicine arrangement, management company model may be an option.
  – Professional corporation is responsible for clinical functions.
  – Management company is responsible for non-clinical functions under management services agreement.
Management Company

“MC”

Administrative Services

Professional Corporation

“PC”

Management Fee

MD, NP or PA Owner(s)
Corporate Practice of Medicine

• Management Services Agreement:
  – Long-term
  – Restrictions on termination
  – Restrictive covenant
  – Management fee
  – Management company handles all non-clinical matters
Corporate Practice of Medicine

• Risks with management company model:
  – Owners may seek to void the management services agreements
  – May be viewed as a sham
  – Licensing board issues
Fee-Splitting

• Many States Prohibit Fee-Splitting
  – Perceived danger of allowing professionals and non-professionals to share in income from professional services:
    • Temptation to maximize profit through medically unnecessary services.
    • Temptation to limit medically necessary services to maximize income.
Federal Anti-Kickback Statute

• Prohibits offering, paying, soliciting or receiving any remuneration in return for
  – business for which payment may be made under a federal health care program; or
  – inducing purchases, leases, orders or arranging for any good or service or item paid for by a federal health care program.

• Remuneration includes kickbacks, bribes and rebates, cash or in kind, direct or indirect.
Federal Anti-Kickback Statute

• Potential penalties for violations of anti-kickback statute:
  – Criminal and civil penalties
  – Imprisonment
  – Civil Monetary Penalties
  – False Claims Act exposure
Federal Anti-Kickback Statute

• Telemedicine relationships requiring anti-kickback analysis:
  – Relationships with supervising/collaborating physicians
  – Relationships with other entities (management company, telemedicine entity, etc.)
Federal Anti-Kickback Statute

• No issue if federal health care program reimbursement is not involved.
  – BUT remember to consider state anti-kickback prohibitions.
• Safe harbor protection
• Advisory opinions
Self-Referral Prohibitions

• Federal Stark law prohibits a physician from making a referral for designated health services (“DHS”) to an entity with which the physician (or an immediate family member) has a financial relationship, unless one of its many exceptions applies.

• Stark also prohibits entities from submitting claims for DHS provided pursuant to a prohibited referral.
Self-Referral Prohibitions

• Stark is a strict liability statute, meaning that the intent of the parties is irrelevant for purposes of determining whether the law has been violated.

• Stark provides for monetary penalties and requires the refund of amounts paid for illegally referred DHS.
Malpractice Risks

• Telemedicine/Online Consultations
  – What is the standard of care?
  – One example: *Hageseth v. The Superior Court of San Mateo County*, 59 Cal. Rptr.3d 385 (Cal. Ct. App. 2007).

• Must consider malpractice coverage
Risk Management

• Peer Review
  – Robust physician supervision/chart review
• Monitor developments in clinical practice guidelines
  – Use evidence-based treatment guidelines
• Check with insurance carrier
• Limit scope of practice/services offered online
• Address continuity of care
Recent Telemedicine Guidelines

• Federation of State Medical Board (FSMB) recently adopted new model policy on use of telemedicine.

• AMA also released new guidelines regarding telemedicine services in June, 2014.
  – Unlike FSMB policy, AMA guidelines do not address standards for prescribing, patient informed consent, or financial conflicts of interest.
FSMB Model Policy

• Defines “telemedicine”
  – “The practice of medicine using electronic communications, information technology or other means between a licensee in one location, and patient in another location with or without an intervening health care provider.”

• Outlines “direct-to-consumer” approach
FSMB Model Policy

• Identifies requirements for establishing a physician-patient relationship.
• Emphasizes need for continuity of care and referral for emergency services.
AMA Recommendations

• Divides telemedicine into three categories:
  – Real-time interaction through an online portal;
  – Remote monitoring through devices; and
  – Store-and-forward practices.

• Recommends telemedicine services be covered and paid for if certain conditions are met (physician-patient relationship, state licensure, compliance with evidence-based guidelines, patient history, care coordination, emergency referral protocol, transparency, etc., etc.)
Questions?