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.

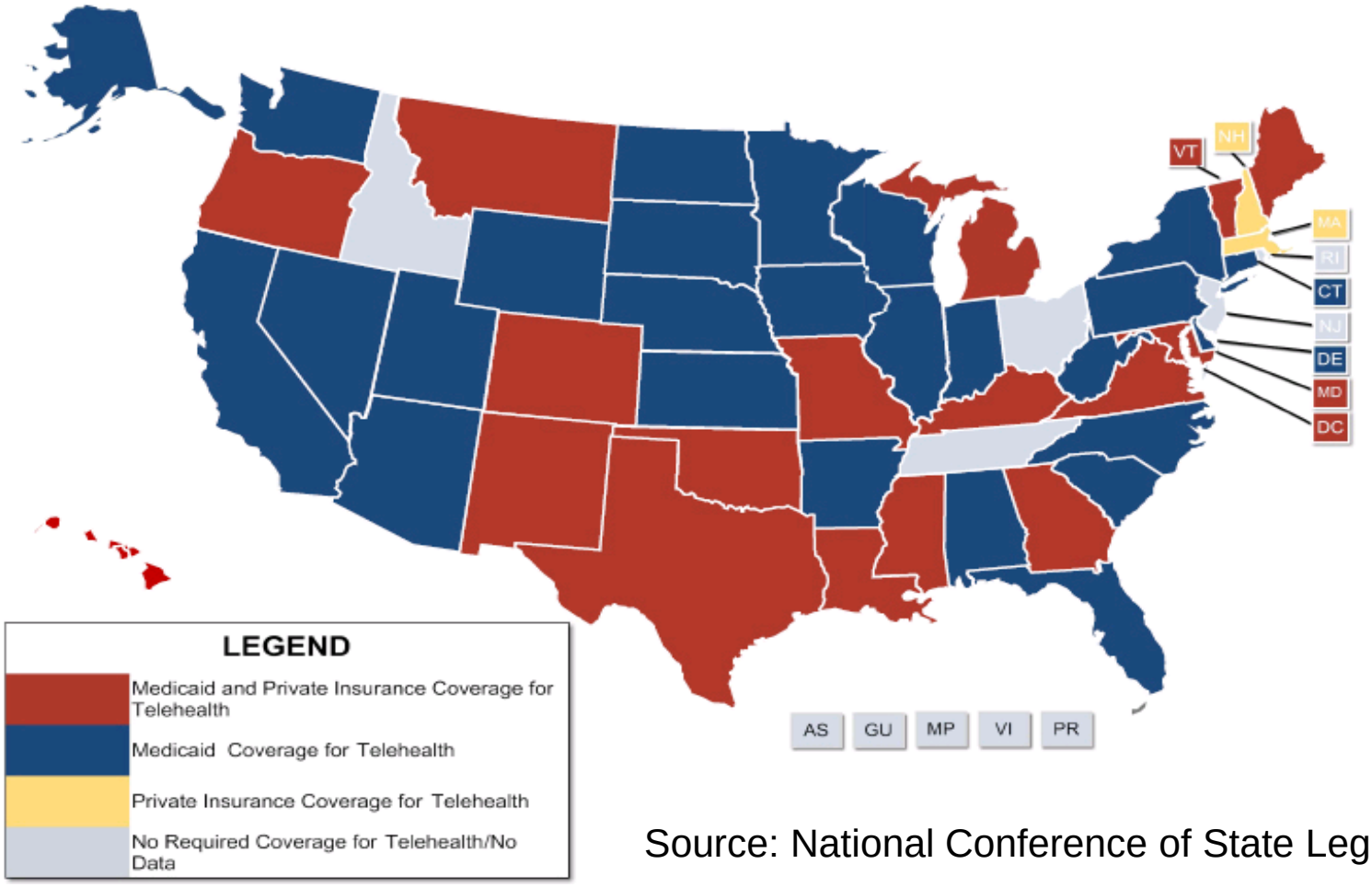
Reimbursement

- 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:
  - http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/documentation.aspx#.UcsKfZwzZke

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

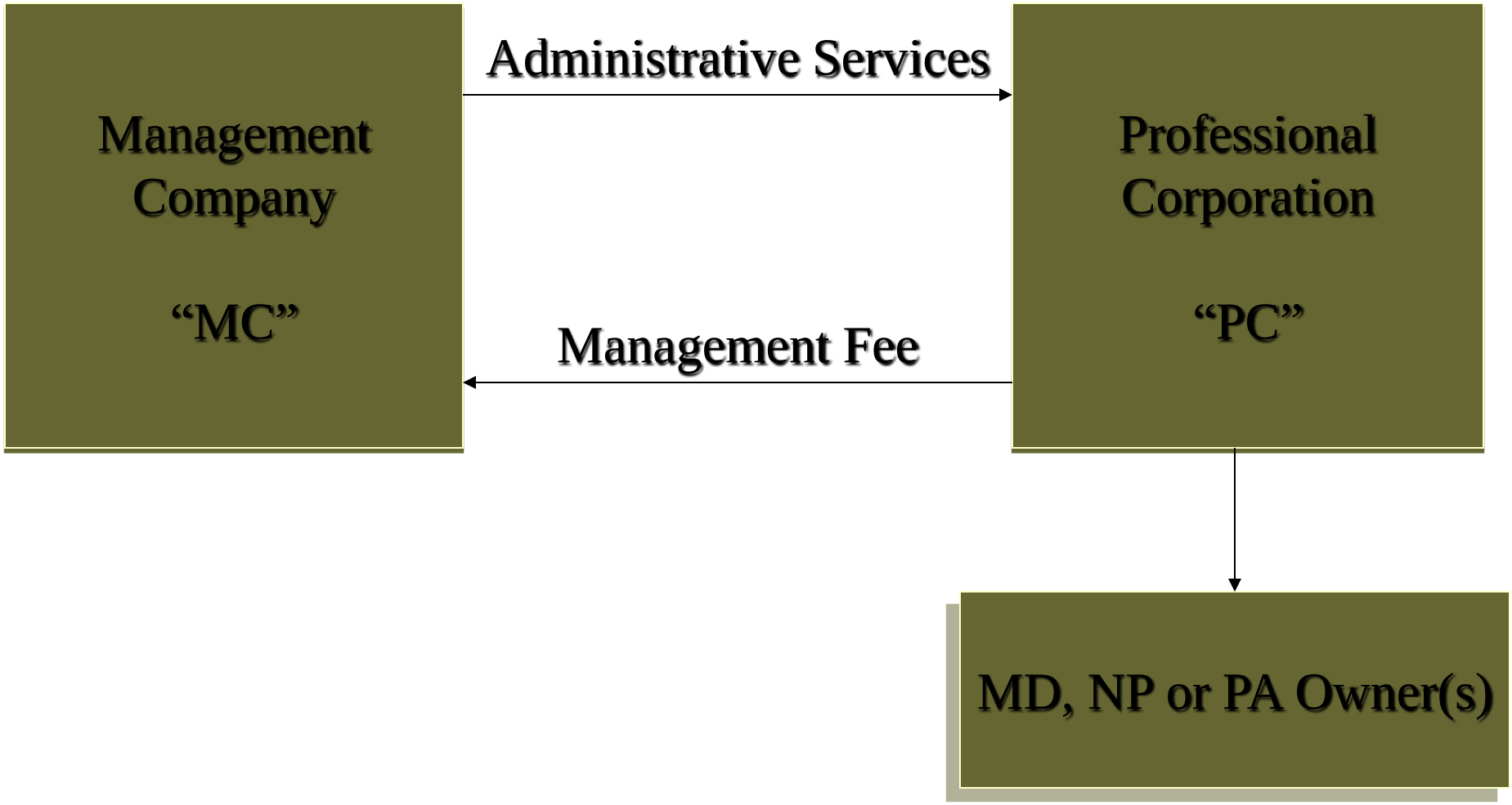
- Based on state statute, case law, attorney general opinions, board policies, etc.
- Enforcement of CPM prohibition varies
  - Some states are more active (e.g., CA, NY)
- Exceptions vary by state
  - Hospitals
  - Entities owned solely by licensed professionals

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.



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,.)

Questions?