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Compliance
Priorities in
Telehealth

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Agenda

- Overview of telehealth regulatory issues
- Risks and Opportunities
  - Technical Risks
  - Privacy & Security
  - EMTALA
  - Fraud & Abuse
  - DOJ Enforcement
- Practical Advice

"We now feel it's cheaper to do surgery via Skype. So, go home and lie down in front of your computer."

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Telehealth Regulatory Overview

What are the current rules?

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Licensure

- Look at licensure laws of *state where patient is physically located*
  - Georgia – formerly required full state license to practice medicine (O.C.G.A. § 43-34-31)
  - Exceptions for:
    - Physician-to-physician consultations
    - Occasional (rather than routine) services
    - Emergency consultations
    - Free consultations
    - Consultations to a Georgia medical school
  - 2019 developments:
    - Telemedicine License
    - Interstate Medical Licensure Act

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Scope of Practice

- Must establish a valid provider-patient relationship
- NPs and PAs typically permitted – must have "demonstrated competence in the provision of care by telemedicine"
- Should make "diligent efforts" to have patient seen in person annually
- Same standard of care as in person:
  - "That which, under similar conditions and like circumstances, is ordinarily employed by the medical profession generally."
  - *Cope v. Evans,* 329 Ga.App. 354, 765 S.E.2d 40 (Ga. App. 2014)

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Establishing the Provider-Patient Relationship

- Georgia – must:
  - Have personally seen patient;
  - Provide care at request of another MD/DO/NP/PA who has personally seen patient; or
  - Be "able to examine the patient using technology or peripherals that are equal or superior to an examination done personally by a provider within that provider's standard of care."
- Ga. Comp. R. & Regs. r. 360-3-.07

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Prescribing

- Cannot prescribe controlled substances or dangerous drugs based solely on consultation via electronic means, except for ~~72 hour~~ 30 day supply or pursuant to valid physician-patient telemedicine relationship
- Federal Law (Ryan Haight Act) – cannot prescribe controlled substances without at least one in-person evaluation, except:
  - Patients located at DEA-registered hospital or clinic;
  - Treatment in physical presence of DEA-registered practitioner;
  - Special registration to engage in the practice of telemedicine (none yet);
  - Other technical exceptions.

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HIPAA, Privacy, Security, and Record Keeping

- Should have appropriate Business Associate Agreement (BAA) with the telemedicine technology vendor
- Implement "reasonable safeguards" to ensure that incidental disclosures are kept to the "minimum necessary"
- Periodic security risk analyses to identify possible vulnerabilities to ePHI and implement security measures
- Stricter requirements for:
  - School-based telehealth settings: Family Educational Rights & Privacy Act (FERPA)
  - Substance abuse treatment: 42 C.F.R. Part 2
  - Psychotherapy notes
- Informed Consent – many states require specific elements be documented

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Billing & Reimbursement
Medicare

- 5 basic requirements (42 C.F.R. § 410.78):
  1. **Geographic location**
     - Rural Health Professional Shortage Area or outside of a Metropolitan Statistical Area
     - Exceptions: ESRD, telestroke
  2. **Originating site**
     - Physician/practitioner office, hospitals, FQHC, SNF, etc.
  3. **Distant site provider**
     - Physician, NP, PA, LCSW, etc. (no location requirement)
  4. **Qualifying technology**
     - Synchronous, live interactive audio/video allowing for "real time" communication
  5. **Covered telehealth service (CPT code list)**
     - 101 services listed for CY 2020
     - Teleradiology and remote patient monitoring are not considered telehealth
- Originating site facility fee can be billed as well as distant site provider professional fee

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Billing & Reimbursement
Georgia Medicaid

- Elements (Telemedicine Guidance Manual, 2019):
  1. **Originating site**
     - Physician/practitioner office, hospitals, FQHC, SNF, Local Education Authorities and School Based Clinics, ambulances, pharmacies, etc. (broader than Medicare)
  2. **Distant site provider**
     - Includes dentists, dental hygienists, audiologists, etc. (broader than Medicare)
  3. **Qualifying technology**
     - Synchronous, live interactive audio/video allowing for "real time" communication
  4. **Covered telehealth service (CPT code list)**
- No rural geographic location limitation
- Written informed consent is required
- Must be HIPAA-compliant and use acceptable method of encryption

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Billing & Reimbursement
Private Payors

- 45 states have some kind of telemedicine parity law – equal coverage
  - Some only among a defined list of services
- 6 states have payment parity – equal payment
- Georgia – previously an equal coverage state
- As of January 1, 2020:

An insurer shall reimburse the treating provider or the consulting provider for the diagnosis, consultation, or treatment of the insured delivered through telemedicine services ***on the same basis and at least at the rate*** *that the insurer is responsible for coverage for the provision of the same service through in-person consultation or contact . . . Payment for telemedicine interactions* ***shall include reasonable compensation to the originating or distant site for the transmission cost*** *incurred during the delivery of health care services.*

O.C.G.A. § 33-24-56.4(f)

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Billing & Reimbursement
Remote Patient Monitoring

- Typically not considered a telemedicine service, but still may be reimbursable
  - Inherently non face-to-face
- Medicare:
  - Initial setup, device, and professional time (may be "incident to" physician's services)
  - Several codes for "Remote Physiological Monitoring" and "Chronic Care Management"
  - Generally requires:
    - Initiating visit
    - Structured recording of patient information using Certified EHR technology
- Medicaid: 22 states reimburse for some form of RPM (not Georgia)

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Risks (and Opportunities)

What can go wrong?

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Technical Risks
Payment in Full and Anti-Supplementation Rule

- Medicare Assignment: "Payment in Full" Rule
  - A provider accepting assignment means the provider accepts the amount paid as payment in full for the items or services rendered
  - Payment will be made directly to the provider
- Anti-Supplementation Rule
  - Provider may not seek additional payments (beyond Medicare / Medicaid) from any other person except for any cost-sharing obligations
  - Violation of Assignment Rule: CMPs, FCA actions, exclusion
- May accept payment from originating site in addition to any amounts telehealth provider may bill/collect from payors only if in connection with on-call coverage, availability, convenience, quality, clinical integration, and similar benefits – not specific health care services already covered by Medicare (or other payors)

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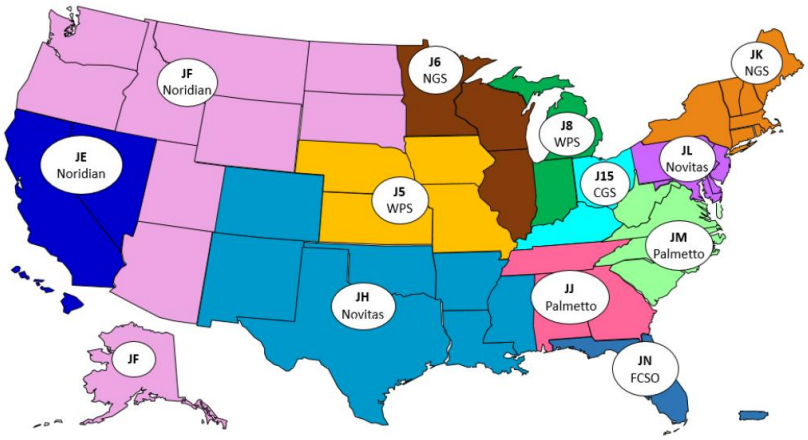
Technical Risks
Reassignment Requirements



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Technical Risks
Reassignment Requirements

- Special rules for interjurisdictional reassignment
  - *Reassignor licensed and enrolled in own state*. The reassignor must be properly licensed in his or her own practice location (office or even home) and enrolled in that MAC jurisdiction.
  - *Reassignor licensed where services rendered*. The reassignor does not need to enroll in the MAC jurisdiction where the reassignee is located or be licensed in the reassignee's state (unless he/she is performing services in that state), but the reassignor must be licensed in the state where patient is located.
  - *Reassignee enrolls in own and reassignor's jurisdiction*. The reassignee must enroll with the MAC where it is located and where the reassignor is located (although does not need to be licensed in the reassignor's state). When enrolling in the reassignor's state, the reassignee should select the practice location type in CMS 855B, Section 4A and select "Other health care facility" and specify "Telemedicine location."
- Should have direct contractual relationship between reassignee and billing entity

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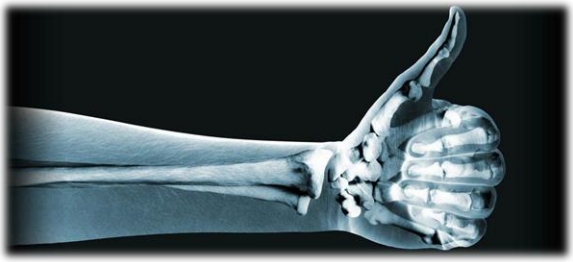
Technical Risks
Anti-Markup Rule

- May not "mark up" diagnostic services fees of providers that do not "share a practice" with billing provider
  - Same office as billing provider, or
  - Provides at least 75% of their professional services through billing provider
- AMR claims must be noted as purchased service on CMS Form 1500
- Teleradiology



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Technical Risks
Licensure

- Ensure state license or an exception
  - Consider mechanism to verify
- State NP or PA supervision rules for physician supervising
- Reading x-rays from overseas
  - See state requirements

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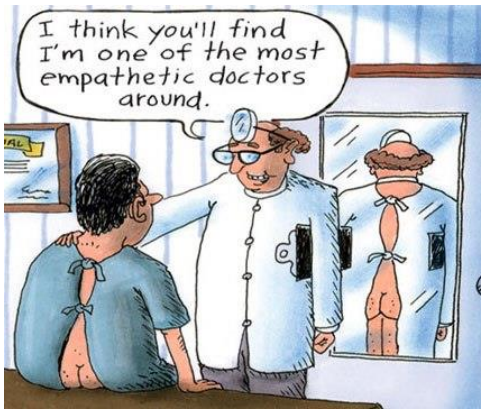
Technical Risks
Physician-Patient Relationship

- Relationship should be established according to state law before treatment/prescribing
- Depends on issue
  - Telemedicine must be clinically appropriate according to provider's clinical judgment and technology available
- Not everyone embraces it
  - Quality of care concerns
  - Patient buy-in and physician buy-in
  - But standard of care should be the same
- Consider/avoid patient complaints
  - Some states require medical board complaint contact information on informed consent form



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Technical Risks
Billing for Emerging Technologies

- Managing emergent care needs to avoid ER or hospitalization
- Reimbursement for check-ins
- Payment is catching up with technology
- CMS is understanding if it keeps patient out of hospital and uses less resources
- Remote patient monitoring – billing changes annually

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Technical Risks
Consultations

- Second opinions or specialist consults
  - Extensions of curbside telephone consults
  - May not be billed (cannot bill for second consult of same specialty in same day)
  - Professional courtesy
- Liability / malpractice concerns
  - Especially if existing patient
- Log, phone note, or medical record should be created
  - Consultative physician's advice may be different than what calling physician hears/does
- Billing – Medicare codes for Remote Interprofessional Consultations
  - Patient co-pay is required

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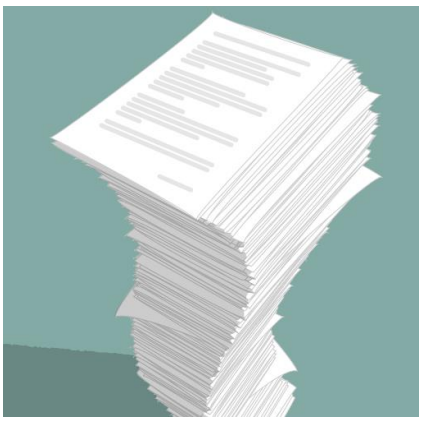
Privacy & Security Risks
HIPAA

- Covered entity versus business associate
  - Specify in contract
- Notice of Privacy Practices
  - Ensure it is made available by a party
- Indemnification for other party's breaches



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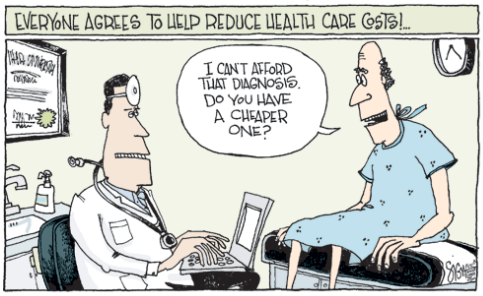
Emergency Medical Treatment & Labor Act
EMTALA

- Hospital must have on-call physicians available to provide treatment necessary after initial examination to stabilize individuals with emergency medical conditions in accordance with resources available to the hospital.
- Hospital must have written policies & procedures to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control.
- Telemedicine can to assist in EMTALA obligations
  - Consult with another physician
  - Exchange imaging studies, laboratory results, EKG's, real-time audio and video, or other clinical information
  - Remote physician may be on hospital's on-call list
- If on-site physician calls specialist in, must come in
- **Do not put on on-call list if they cannot come in**
- CAHs – telemedicine physician can certify transfer



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Fraud & Abuse
Anti-Kickback Statute and Stark Law

- Concerns that payments or the provision of technology could constitute kickbacks or create non-compliant financial relationships
- Structure to comply with Personal Services &/or Equipment Rental safe harbor
  - Require fair market value and commercial reasonableness
- OIG Advisory Opinions 98-18, 99-14, 04-07, 11-12, & 18-03 – **typical safeguards**:
  - Patient freedom of choice;
  - No advertising for free services;
  - Consultations do not result in claims to federal payors;
  - Telemedicine programs that support and expand access to care, especially specialist access in rural areas;
  - Follow up referrals are sent to other primary care physicians;
  - Public benefit by promoting access;
  - Referrals are not required;
  - Partners not chosen based on referral history.

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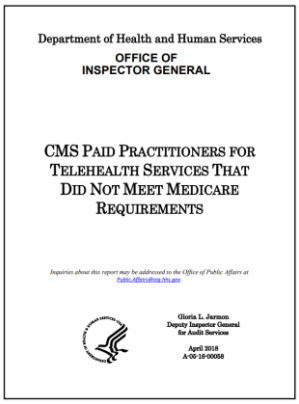
Fraud & Abuse
OIG 2018 Report

- "CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements" (https://oig.hhs.gov/oas/reports/region5/51600058.asp)
- Findings:
  - 31% of claims sampled did not meet Medicare Conditions for Payment
  - 24 of the claims were unallowable, beneficiary at nonrural originating sites
  - 7 billed by ineligible institutional providers
  - 3 for patients at unauthorized originated sites (homes)
  - 2 services provided by unallowable means of communication
  - 1 noncovered
  - 1 performed by a physician outside the U.S.
- Recommended:
  - CMS conduct periodic postpayment reviews to disallow payment for errors for which prepayment edits cannot be implemented;
  - Work with MACs to implement claims edits; and
  - Offer education and training to practitioners on requirements.


Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL

CMS PAID PRACTITIONERS FOR TELEHEALTH SERVICES THAT DID NOT MEET MEDICARE REQUIREMENTS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov

Gloria L. Jarmon
Deputy Inspector General for Audit Services

April 2018
A-05-16-00058

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Fraud & Abuse
Behavioral Health Care Audit

- "Telehealth to Provide Behavioral Health Services in Medicaid Managed Care" (https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000397.asp)
- Focusing on selected states
- Analyzing how states and MCOs use telehealth to provide behavioral healthcare
- Reviewing states' monitoring and oversight of MCOs' behavioral telehealth services
- Identifying states' and MCOs' practices on how to maximize the benefits and minimize the risks of providing behavioral healthcare via telehealth

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DOJ Enforcement
US ex. rel. Cohen v. Anton Fry and CPC Associates

- Federal District Court in Connecticut – Settled 2016
  - Connecticut psychiatrist agreed to pay $36,704
  - Allegedly billed Medicare for services provided over the phone
  - Services did not meet the Medicare definition of telehealth
  - Were not provided in approved sites
  - Did not include face-to-face, interactive audio and video telecommunications systems that enable real-time communication between the distant-site provider and the patient at the originating site
- Whistleblower suit brought by the patient
  - Fry spoke to patient by phone for about 5 minutes on Oct. 2, 2012, and allegedly billed Medicare twice for a psychiatric diagnostic interview examination and was paid $255.

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DOJ Enforcement
Operation Brace Yourself

- April 2019
- 130 DME companies that had submitted over $1.7 billion in claims and were paid over $900 million

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DOJ Enforcement

Operation Brace Yourself

- CEO of DME company in Savannah
  - Sentenced May 3, 2019
  - 40 months in prison and repay almost $2 million
- CEO of telemedicine company
  - September 2019
  - Ordered to pay $200 million restitution

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DOJ Enforcement
Operation Double Helix

- Telemarketing company offered free genetic testing to patients with any family history of cancer
- Doctors write prescription for genetic tests
- Often never sent results or gave consults to beneficiary
- Medicare reimbursement—from $10,000 to $18,000 or more—split between:
  - Patient recruiter,
  - Doctor writing prescription,
  - Lab doing test,
  - Telemarketing company that organized the alleged scheme.
- Charges against 35 individuals associated with dozens of telemarketing companies and testing labs
- 9 doctors charged
- DOJ says it cost the Medicare program more than $2 billion in unnecessary charges

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DOJ Enforcement
Common Threads

- Lack of medical necessity
- Payment of kickbacks to patient recruiting companies
- Vulnerable populations

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Practical Advice

Now what?

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Takeaways

- Good understanding of rules
- Compliance Program
- Train employees
- Compliance officers can shadow telehealth visits – learn about technology and how your system is using telehealth
- Periodic audits

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