How to Stay Synchronous with Telehealth Compliance Rules

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Agenda

- Compliance opportunities in the telehealth regulatory landscape
- Changes to CMS telehealth regulations – opening the gates
- Controlled substance prescribing – the DEA
- Results of the 2018 OIG audit of CMS telehealth payments

Digital Health

- Virtual Care (including Telehealth, Telemedicine, Telemonitoring, etc.)
- Electronic Messaging
- Artificial Intelligence (Machine Learning)
- Wireless Medical Devices
- Mobile Medical Apps
- Health IT
- Medical Device Data Systems
- Software as a Medical Device (SaMD)
- Cybersecurity

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Telemedicine: Do We Have a Definition?

- Communication with patient or consulting provider from remote location to provide care to patient
  - Store & Forward
  - Real Time (Synchronous)
  - Remote Monitoring



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Telehealth and Telemedicine in Texas

- **Telehealth** - health service, ***other than a telemedicine*** medical service, delivered by health professional licensed, certified, or otherwise entitled to practice in this state and acting within the scope of the health professional's license, certification, or entitlement to a patient at a different physical location than the health professional using telecommunications or information technology.
- **Telemedicine** - health care service delivered by a ***physician*** licensed in this state, ***or a health professional acting under the delegation and supervision of a physician*** licensed in this state, and acting within the scope of the physician's or health professional's license to a patient at a different physical location than the physician or health professional using telecommunications or information technology.

Compliance Opportunities in the Telehealth Regulatory Landscape

Regulations Governing Telehealth

- **Professional Conduct**
  - Physician Licensure – Interstate Medical Licensure Compact
  - Prescriptions – DEA and Ryan Haight Act
  - State Medical Board Regulations
    - Informed Consent
    - Physician-Patient Relationship
  - Malpractice and Insurance
- **Technology**
  - FDA – medical devices
  - FCC – wireless spectrum
- **Data Privacy and Security**
  - OCR – HIPAA/HITECH
  - FTC – Breach Notification Rule
  - ONC – standard development & coordination
  - State Privacy and Security Laws
- **Compliance**
  - Stark
  - Anti-Kickback
  - State law

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Licensing

- Generally must have a medical license issued by state where patient is located
  - FSMB Interstate Medical Licensure Compact designed to facilitate licensure applications across state lines
- Establishment of Physician-Patient Relationship
  - Registration – ID
  - "Face-to-Face"?

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Selected Texas Telemedicine Guidelines

- Same ***standard of care*** as in-person setting
- Establish "***practitioner-patient relationship***"
- Physicians required to have ***license*** in state where patient is physically located
- Issuing ***prescription*** subject to same requirements as in-person although Federal limitations (**Ryan Haight Act**) exist for controlled substances
- Same "***adequate medical record***" obligation as in-person
- ***Consent and notice of privacy practices***

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Telemedicine Reimbursement Checklist for Managed Care Contracting

- ❑ **Real Time Communication**: Payers may require services be provided via real-time communication & may exclude phone/email
- ❑ **Patient Location**: Payers may require patient be located in rural area (similar to Medicare) or at a "patient-site" facility
- ❑ **Provider Licensing**: Provider should be licensed in state patient is located in (or have a limited telemedicine license)
- ❑ **Provider Eligibility and Credentialing**: Payers may require specific credentialing for telemedicine
- ❑ **Prior Authorization**: Payers may require prior authorization for telemedicine services
- ❑ **Claim Submission**: Payers may have limited telemedicine billing codes

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Credentialing by Proxy

- CMS Conditions of Participation and The Joint Commission
- Originating site may rely on the credentialing and privileging of the distant site through a written agreement
  - Distant site hospital must be a Medicare and Joint Commission participant;
  - Physician must be privileged at the distant-site hospital;
  - Physician holds a license in the state where the originating site is;
  - Originating site has evidence of internal review of the physician's performance of these privileges; and
  - The distant site's medical staff credentialing and privileging process and standards meets the CMS Conditions of Participation requirements and The Joint Commission standards.

Technical Risk Management

- Carefully vet and select your channel provider
- Regardless of conduit exception, frame your channel provider's responsibilities by contract:
  - security controls & safeguards, including whether transmission data is encrypted per HIPAA standards
  - data storage and access
  - Permitted uses/disclosures
  - Incident/breach responsibilities, liability/indemnity, & cyber insurance
- Update your risk assessment and security controls
- Review/update your privacy notices & patient authorizations
- Update your incident/breach response plans

Changes to CMS Telehealth Regulations – Opening the Gates

2019 Physician Fee Schedule

Brief Communication Technology-based Service, e.g. Virtual Check-in

- When a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology to assess whether the patient's condition necessitates an office visit
- Reimbursed at $14
- Code G2012
- Copays apply
- Not labeled telehealth, therefore not subject to telehealth restrictions
- FQHC/RHCs will receive own code for this service
- Informed consent required

2019 Physician Fee Schedule

Asynchronous Remote Evaluation of Pre-Recorded Patient Information

- Remote professional evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology
- Must be an established patient
- Code G2010
- Copays apply
- Not labeled telehealth, therefore not subject to telehealth restrictions
- FQHC/RHCs will receive own code for this service
- Informed consent required

2019 Physician Fee Schedule

Interprofessional Internet Consultation

- Cover consultations between professionals performed via communications technology such as telephone or Internet
- 99446-99449, 99451, 99452
- Verbal consent and acknowledgement of cost sharing from patient required
- Limited to practitioners that can independently bill Medicare for E/M visits
- Not allowed for FQHC/RHC because AIR and PPS rates already includes costs of consults with other practitioners

2019 Physician Fee Schedule

Additional Changes

- Add HCPCS codes G0513 and G0514 as codes to be reimbursed if telehealth is used. Would be subject to the telehealth restrictions
- Made changes required by Bipartisan Budget Act of 2018
- For remote pyshiological monitoring: codes created and finalized to be reimbursed: 99453, 99454 and 99457
- For chronic care management: new code for reimbursement 99491

Controlled Substance Prescribing – the DEA

Online Prescriptions

- Ryan Haight Act
  - Enforced by the DEA
  - Applies to controlled substances
  - A controlled substance cannot be dispensed without a "valid prescription" unless a telemedicine exception applies
  - “Valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by (i) a practitioner who has conducted at least one (1) in-person evaluation of the patient, or (ii) a practitioner that is providing coverage services via telemedicine for a physician that has perform at least one (1) in person exam within twenty-four (24) months
  - Telemedicine Exception – online prescriptions valid if the distant site provider is registered with the DEA and the patient is located in a hospital/clinic properly registered with the DEA

Results of the 2018 OIG Audit of CMS Telehealth Payments

2018 OIG Report on Telehealth Services

- 2014-215 audit period, focused on claims without matching originating site fee
- 69 out of 100 audited claims met requirements
- Remaining 31:

- 24 claims at nonrural originating sites
- 7 claims by ineligible institutional providers
- 3 claims at unauthorized originating sites
- 2 claims by an unallowable means of communication
- 1 claim for noncovered service
- 1 claim by a physician located outside the United States
- OIG: Medicare could have saved $3.7 million during audit period if practitioners had provided telehealth services in accordance with Medicare requirements

Article: https://oig.hhs.gov/oas/reports/region5/51600058.pdf

Telemedicine Fraud & Abuse

- State & federal fraud & abuse laws
  - Anti-Kickback Statute (AKS): prohibits knowingly paying, offering, or soliciting referrals or services reimbursed by CMS
  - Stark: prohibits physician from referring Designated Health Services (DHS) to entities physician has financial relationship with
  - State-specific fraud and abuse laws
- AKS safe harbors and Stark exceptions may apply to telemedicine
  - Limited guidance from HHS & OIG regarding applicability
- Telemedicine arrangements may involve sharing equipment with unrelated entities
- Analyze whether arrangements implicate state and federal fraud and abuse laws

Telemedicine Fraud & Abuse

1. *1994 OIG Fraud Alert*: Lab's provision of free computers & fax machines to physicians could implicate AKS unless items are necessary to provide lab services & used only to coordinate lab services
2. *1998 OIG Opinion*: Physician's provision of free telemedicine consultations & leased equipment to another physician did not violate AKS
   - Lease arrangement met AKS safe harbor
   - Arrangement unlikely to produce referrals
3. *2004 OIG Opinion:* Health system's provision of telemedicine equipment to school-based clinics did not violate AKS if students only received screening services & referred to regular provider for follow-up care
4. *2011 OIG Opinion:* Health system's provision of telemedicine consultations and equipment to unrelated hospitals did not violate AKS
   - Arrangement unlikely to produce referrals or increase CMS costs
   - Main purpose to benefit stroke patients with limited access to care

Telemedicine Gone Wrong - Tricare's Compounded Medical Loophole

Tricare bilked by several companies, across four states, handful of providers and hired Marines

- Clinic affiliated nurse practitioner (Tennessee) conducted fake telemedicine visits
- Physicians (Tennessee) wrote scripts
- Pharmacy (Utah) filled pain cream prescription
- Tricare charged $14,500 (started at $40)
- Marines paid $300 per month. Persuaded they were in drug trials.
- Media: Tricare's Compounded
- **Red Flags**: Multiple locations, escalating prices and volumes, conventional fraud scheme on a telemedicine platform

Florida Doctor Recounts her Role in Billion Dollar Telemedicine Scheme

- Tens of thousands of patients, more than 100 physicians, pharmacies in Florida and Texas
- Doctor's story:
  - Retired physician paid $150 per prescription
  - Questionable physician-patient relationship
  - Knee/back braces, pain creams, diabetic supplies
  - Use of credentials without provider's knowledge

Thank You!

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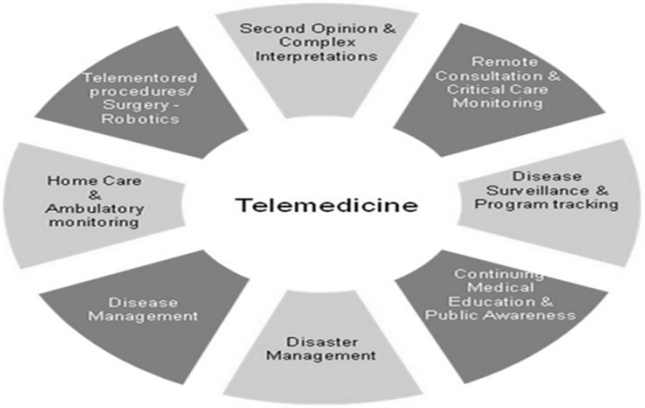
Telemedicine Functionality



Source: tapasvan.me

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