

Telemedicine Heading Into 2020: Updates on Legal, Reimbursement and Compliance Issues

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Today's Webinar

- What is telemedicine?
- Licensure
- Scope of Practice
- Prescribing
- Reimbursement
- Fraud and Abuse
- Informed Consent
- Privacy and Security
- Consumer Protection Laws
- Contract Provisions and Risk Mitigation
- Corporate Practice of Medicine

What is Telemedicine

Telemedicine is the use of electronic communication technologies to provide clinical services to patients without an in-person visit, with the goal of improving the patient's health status. The electronic communications or monitoring may be used for follow-up visits, management of chronic conditions, medication management, consultation with specialists, or other clinical services that can be provided remotely via secure video and audio connections.

How does telemedicine fit into the digital health ecosystem?

Digital Health Broadly



Health Apps



Connected Devices / IoT



Automation and Robotics



Consumer apps and wearables



Clinical Research



Health IT / Services



Telemedicine



Medical Algorithms

Types of Telemedicine

- Store-and-Forward (Asynchronous)
- Remote Patient Monitoring
- Real Time Services

Store-and-Forward (Asynchronous)

- The electronic transmission of patient data among providers at different locations
- A secure way to share information
- Asynchronous – providers do not need to be reviewing the patient records at the same time
- Best suited for consulting with specialists, external resources
- Examples:
 - Teleradiology – a smaller facility can send x-rays to a remote radiologist for review and diagnosis
 - Teledermatology – a primary care physician can take a picture of a skin condition and send to a specialist for consultation
 - E-Consults, second opinions
- Benefits:
 - Patients can obtain specialty care, even if not available in their particular geography
 - Faster, more cost-effective than seeing a specialist

Remote Patient Monitoring

- The collection of health data from a patient in one location, and the transmission of the health data to a provider in a different location
- Can be done with active and live monitoring of information to flag for issues
- Alternatively, providers can receive reports of collated data for better ongoing care
- Often used for chronic care management
- Examples:
 - Monitoring vitals, blood pressure, glucose levels, heart rate, pulse, sleep patterns, weight
 - Information often gathered from wearable and mobile devices
 - Tele-hospitalist, tele-cardiology
- Benefits:
 - Can help identify issues quickly before they develop into bigger problems
 - Can help providers better understand patient behavior
- Risks:
 - Wearable devices – new, unproven applications

Real Time Services

- Live, two-way video encounter between a patient and a provider, or between providers
- “Skype” medicine – but with secure, private connections and HIPAA compliant technology
- Most often used for primary care, urgent care or follow-up issues
- Examples:
 - Patients with suspected pink eye, ear infection, influenza, rash, respiratory infections, lice
 - Tele-Neuro (strokes, sepsis, cardiology)
- Benefits:
 - Convenient, fast, cost-effective for patients
 - Opportunity to get immediate treatment
 - Not limited to physicians in your immediate area
- Risks:
 - Managing patients from distant locations

Types of Telemedicine Agreements

- Telemedicine Services Agreement
- Credentialing and Privileging Agreement
- Equipment Lease or Purchase Agreement
- Technology or Software Licensing or Purchase Agreement
- Technology Service Agreement
- Data Use Agreement
- Business Associate Agreement
- Management Services Agreement
- Collaborative or Supervising Agreement
- Website Terms of Use and Privacy Policy

Telemedicine Statistics

- Kaiser Permanente is a national leader in telemedicine
- In 2015, of KP's 110 million interactions between physicians and members, 56% were virtual, surpassing physical visits for the first time

- Sangarapil Manoharan, M. (2017). Current Capabilities and Moving Forward With Telemedicine Treatment. *National Workers' Compensation and Disability Conference & Expo*, (p. 9).

Legal and Regulatory Issues

Practitioner Licensure

- 48 state medical boards (plus the District of Columbia) require that any physician providing care to patients via telemedicine is licensed in the state where the patient is located.
 - Kansas and New Mexico do not require licensure
- 15 states have special purpose telemedicine licenses
 - Minn. Stat. 147.032 Interstate Practice of Telemedicine
- Exceptions for infrequent or occasional consultations – 28 states
 - 5 states define occasional or infrequent
 - Delaware: fewer than six consults per year
 - New Mexico: no more than 10 patients per year
 - Wyoming: not more than seven days in any 52-week period.

Scope of practice

- Practitioners must limit telemedicine practice to what is within the practitioner's scope of practice
- Practitioners must also pay attention to what each state permits a practitioner to do
 - I.e., some states require in-person encounters before providing telemedicine
 - Definitions of “practicing medicine” or “telemedicine” may differ

Scope of practice

- Scope of practice is particularly important for non-physicians
 - Many states permit non-physicians to practice telemedicine
 - Others are silent
 - Scope of practice for non-physicians varies by state
 - If there are supervision requirements for non-physicians, who provides the supervision for the practitioner?
- Standard of care

Telemedicine and prescribing

- Most prescribing statutes were written before widespread use of telemedicine
- State statutes are vague
- Many states require a physical exam or pre-existing physician-patient relationship prior to prescribing

Telemedicine and prescribing

- Minn. Stat. 157.37 (d) A prescription drug order for [controlled substances and certain other drugs] is not valid, unless it can be established that the prescription drug order was based on a documented patient evaluation, including an examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment:
- (e) For the purposes of paragraph (d), the requirement for an examination shall be met if an in-person examination has been completed in any of the following circumstances:
 -
 - (5) the referring practitioner has performed an examination in the case of a consultant practitioner issuing a prescription or drug order when providing services by means of telemedicine.

Telemedicine and prescribing

- Federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008 – designed to combat rogue internet pharmacies selling controlled substances online
 - Prohibited form-only online prescribing for controlled substances
 - Permitted prescribing of controlled substances via telemedicine if practitioner has conducted an in-person exam or meets a “practice of telemedicine” exception (limited to hospitals, registrant in the room)
 - Practice of telemedicine exceptions are outdated. Counter to direct-to-patient service models (e.g., substance use disorder treatment)
 - No “special registration” rules from the DEA
- 2018 SUPPORT Act included the “Special Registration for Telemedicine Act of 2018” requiring DEA to promulgate special registration regulations by October 24, 2019

Reimbursement

- As always, it varies by payer
- Commercial payers: check your contract and the provider manual
- Many states have parity laws:
<https://www.cchpca.org/telehealth-policy/current-state-laws-and-reimbursement-policies#>
- Medicare has specific limitations on telehealth reimbursement

Medicare telehealth

- “Telehealth-delivered services” for Medicare patients are authorized by Section 1834(m) of the Social Security Act
- Section 1834(m) limits the use of telehealth to certain services, providers, technology, and patient locations

Medicare telehealth – who?

- Physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical social worker, clinical psychologist, registered dietitian

Medicare telehealth – what?

- Services on Medicare’s list of covered services “telehealth services”
- Provided via an interactive 2-way telecommunications system (real-time audio and video)
- Asynchronous (i.e., store and forward) only permitted in Alaska and Hawaii demonstration projects

Medicare telehealth – where?

- Patient must be located in one of the following “originating sites”: doctor's office, hospital or critical access hospital RHC, FQHC, hospital-based dialysis, SNF, or CMHC
- Originating site must be (1) outside of an MSA or (2) in a HPSA

Medicare telehealth – where?

- Patient may be at home only in certain circumstances
 - End-stage renal disease patients who are getting home dialysis;
 - SUD or co-occurring mental health disorder (see below)
- Effective July 1, 2019, telehealth for substance abuse or co-occurring mental health disorder can be furnished in any jurisdiction, and at the patient's home.

Medicare telehealth – where?

- New in 2019: Acute stroke telehealth services may be provided anywhere (no geographic or originating site restrictions)

Medicare telehealth billing

- Originating site facility fee (no fee for home)
- Distant site practitioner charge
 - Same payment as in-person service under the Medicare Physician Fee Schedule
 - Place of Service (POS) 02-Telehealth
 - Submit to practitioner's MAC

CY 2019 Updates

- CMS added the following to the list of covered telehealth services:
 - Prolonged preventive service(s) (HCPCS codes G0513 and G0514)
- Added renal dialysis facilities and homes as originating sites for ESRD-related assessments
- Added mobile stroke units as originating sites without geographic requirements

Communication Technology Based Services (CTBS) (i.e., NOT telehealth)

- CMS has attempted to increase access to physician services routinely furnished via communication technology
 - Not subject to limitations on Medicare telehealth services
- For CY 2019, CMS added the following:
 - Brief communication technology-based service, e.g. virtual check-in (HCPCS code G2012)
 - Remote evaluation of recorded video and/or images submitted by an established patient (HCPCS code G2010)
 - Interprofessional internet consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449)

CY 2020 Telehealth Updates

- For telehealth services, added bundled episodes of care for treatment of opioid use disorders:
 - G2086: *Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*

CY 2020 Telehealth Updates

- *G2087: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- *G2088: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

Fraud and abuse

- Telemedicine arrangements must comply with federal and state fraud and abuse laws
 - Federal and anti-kickback statutes and self-referral prohibitions
- Office of Inspector General advisory opinions provide valuable guidance for providers and entrepreneurs when structuring telemedicine arrangements

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, equipment/technology vendor, 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
 - space rental, equipment rental, personal services and management contracts, etc,
- Advisory opinions

Fraud and abuse

- Historically favorable treatment of telemedicine arrangements in OIG advisory opinions
 - AO No. 98-18 Ophthalmologist and optometrist equipment lease
 - AO No. 99-14 Health system and rural facilities partnership following expired telemedicine grants
 - AO No. 04-07 Health system and school-based clinics
 - AO No. 11-12 Telestroke program
- 2018 Advisory Opinion (No. 18-03)
 - FQHC provided free equipment to county clinic for telemedicine encounters related to HIV prevention
 - OIG: AKS implicated but no sanctions

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Patient consent

- Some states require special consent
- Additional issues to consider
 - Providing names, credentials, and associations of all health care providers involved
 - Description of technology used in encounter
 - Risks specific to electronic nature of care delivery (e.g., lost connection, limitations of technology)
 - Security and privacy issues and precautions
 - Plan for ongoing care, location of health records
 - Prescribing limitations
 - Alternatives to telemedicine encounter

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

- Telemedicine providers billing for telemedicine services must
 - comply with HIPAA and state confidentiality and privacy rules for protection of protected health information
 - ensure policies and procedures are in place to prevent unauthorized use or disclosure
 - provide notice of a breach when needed

Privacy and Security

- Telemedicine Providers must maintain:
 - Business Associate Agreements
 - Patient Consents
 - Patient Rights for Telehealth Encounters Forms

Direct to Consumer Advertising

Advertising Laws



- FDA
- Federal Trade Commission
 - FTC consumer protection law prohibits unfair or deceptive trade practices
 - applies to health claims
 - applies to privacy and security assertions
 - Enforcement actions
 - Lumosity
- State laws

Corporate Practice of Medicine

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

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

Risk Mitigation and Contracting Tips

- Contract considerations
 - Describe arrangement with specificity
 - List of services, types of providers, location of services, support staff, training, maintenance of licenses and credentialing, etc.
 - Technology requirements
 - Purchasing, installing, maintaining equipment; access to support services; training; interoperability
 - Representations and warranties
 - Intellectual property
 - Indemnification
 - Insurance
 - Data issues

Contact Information



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