



Telemedicine is Here!

What Your Clients Need to Know

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Overview

What we're going to cover:

- What is telemedicine?
- Licensure and scope of practice
- Reimbursement
- Compliance and fraud and abuse issues



What is Telemedicine?

Depends on who you ask...



- **Synchronous Communication / Interactive Services**: Real-time interaction between the provider and patient generally via an audio or visual connection. A number of states *only* allow telemedicine through the use of a synchronous connection.
- **Asynchronous / Store-and-Forward**: Transmission of medical data, such as images or video, to a physician for assessment
- **Remote Monitoring**: Devices used to monitor patients, chronic diseases, record vital signs and improve medication adherence



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Telemedicine Examples

Ways healthcare
providers are taking
advantage of
technological
advances

Tele-ICU

**Home
Health:
Remote
Monitoring**

Telestroke

**Second
Opinions**

Nursing

Telemedicine Offers Multiple Advantages

- Improves access to care
- Reduces the cost of health care
- Is in high demand from patients
- Assists with population health management



But Telemedicine Poses a Myriad of Legal and Regulatory Challenges...



Licensure and
Scope of Practice



Reimbursement



Compliance /
Fraud and Abuse



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Licensure and Scope of Practice

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Licensure

Why is licensure important?

- Distant site (where telemedicine provider is located)
 - Subject to criminal or administrative sanctions if not properly licensed
 - No reimbursement for unlicensed services
 - No liability insurance coverage
- Originating site (where patient is located)
 - No liability insurance for provider
 - No reimbursement for unlicensed services
 - Facility licensure problems
 - Issue with compliance with conditions of participation (e.g., CMS hospital COPs require all health care professionals to be legally authorized to practice in the state where the hospital is located)
 - Possibility of negligent credentialing liability if bad outcomes

Licensure

Generally

- State laws generally require that practitioners be licensed by the state in which the patient is located
 - States prohibit the unauthorized practice of medicine
 - “Practice of medicine” is generally occurring where the patient is located
 - State in which patient is located wants to obtain jurisdiction over practitioner providing services
- Full license vs. limited license
- Narrow exceptions
 - Providing services in a federal facility
 - “Consultation” (e.g., physician-to-physician consults)
 - Limited number of patient encounters (e.g., 3 or fewer “visits” with patients in a state during a calendar year)

Interstate Medical Licensure Compact

- Offers new, expedited pathway to licensure for qualified physicians in multiple states
 - Helps eliminate some of the burdens and costs associated with full licensure in each state
 - States participating in the Compact agree to share information and work together to streamline the licensure process
- Physicians applying for expedited licensure through the Compact will be granted a full, unrestricted license to practice medicine in the state
- 24 states currently have passed required legislation (though not all have implemented the required processes), with at least 5 additional states having pending legislation

Interstate Medical Licensure Compact

Requirements – physicians must:

- Possess a full, unrestricted license in a Compact state
- Have no discipline on any state medical license
- Have no discipline related to controlled substances
- Not be under investigation by any licensing or law enforcement agency
- Passed required examinations and successfully completed a graduate medical education program

Scope of Practice

What is required for an in-person examine?

- State specific
 - Certain technology (e.g., real-time audio visual)
 - Prior physician-patient relationship including prior in-person exam
 - Meeting established standard of care
 - Same standard of care for in-person exam as exam provided via telemedicine

Scope of Practice

Prescribing requirements

- Many states require in-person encounter, including a physical exam, prior to prescribing medication electronically
- Must ensure appropriate patient-provider relationship has been established
- Before prescribing practitioners should check:
 - Medical practices acts
 - Medical board statements
 - Pharmacy board statements
 - Laws regarding in-person contact

What About Nurses?

- Need to review and comply with Nurse Practices Act for each state where patient may be located
- Confirm whether the Act includes any specific requirements or guidance regarding the provision of services via telemedicine

What About Nurses?

Nurse Practitioners

- Similar to physicians, need a license for each state where patients will be located
- Efforts under way to enact advanced practice registered nurse (APRN) compact, allowing advanced practice nurses to hold one multistate license and practice in compact states
 - Need at least 10 states to enact the legislation before compact goes into effect
- Need to ensure acting within the scope of practice for the state where each patient is located

Nurse Licensure Compact

- Adopted by 31 states (2 of which are pending enactment)
- RNs, LPNs, and LVNs
- Grants reciprocity to practice in participating states without getting a license
- Note: for nurses practicing under the supervision of a physician, physician also needs to be licensed in the state where the patient is located



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Reimbursement

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Medicare Reimbursement

Medicare reimbursement is generally only available for **limited types of services** provided to **rural beneficiaries**.

- In 2016, only \$29 million was paid out for telemedicine services out of \$615 billion paid out for all Medicare programs.
- 108,000 Medicare beneficiaries accounted for over \$300,000 telemedicine visits.
- 56% of users were under 65 years old and 62% were dually eligible (Medicare and Medicaid)
- Most common types of services: physician office services, mental health services, and telestroke.



Medicare Coverage Requirements

Medicare has placed tight restrictions on coverage of telemedicine.

- The patient must be located in a **qualifying rural area** (called, Health Professional Shortage Area);
- The patient must be located at a qualifying “**originating site**”;
- Services must be provided by 1 of 10 **eligible distant site practitioners**;
- Services must be provided over **real-time audio-video feed**; and
- The **CPT/ HCPCS code** for the service must be included on list of covered Medicare telemedicine services.

Recent Legislative and Regulatory Changes

Recent changes allow for increased Medicare coverage for telemedicine.

- **Creating High Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2017 (CHRONIC Act)**
 - **Medicare Advantage Plans** have the option of providing additional telemedicine benefits.
 - Beneficiaries assigned to **Accountable Care Organizations** may receive telemedicine services in their home.
 - Medicare will cover **End Stage Renal Disease (ESRD)-related clinical assessments** to home dialysis patients.
 - Geographic and facility type restrictions on origination sites for **services involving treatment of stroke**.



Medicare CY 2019 Physician Fee Schedule

- Published on July 12, 2018
- Comments due by September 10, 2018
- Proposes significant changes related to telemedicine:
 - **New codes** to the Medicare telemedicine list;
 - Expands telemedicine reimbursement for **end stage renal disease and acute stroke**; and
 - Reimbursement for certain physician services provided via **remote technology communications**.



Medicare CY 2019 Physician Fee Schedule

CMS is proposing reimbursement for additional physician services, which CMS believes fall outside the scope of Medicare telemedicine services.

- **Virtual Check-ins** – brief non-face-to-face check-in to assess whether a patient's condition necessitates an office visit
- **Remote Evaluation of Pre-Recorded Patient Information** – store-and-forward, including interpretation with verbal follow-up with the patient within 24 hours
- **Interprofessional Internet Consultation** – consultations provided by a consulting physician to a treating physician via telephone or internet

Medicaid Reimbursement

Generally Medicaid programs place fewer restrictions than Medicare on telemedicine reimbursement.

- **Interactive Services via Live Video Feed** - 48 states and D.C.
- **Store-and-Forward** – 15 states
- **Remote Monitoring** – 21 states
- 9 states reimburse for **all three types** of services – Alaska, Arizona, Illinois, Minnesota, Mississippi, Missouri, Oklahoma, Virginia, and Washington



State Telemedicine Laws and Medicaid Program Policies



- **Definition** – 49 states and D.C. have a definition for telemedicine
- **Location** – a few states require a certain amount of distance between the provider and patient
- **Consent** – 30 states have informed consent requirements
- **Cross State Licensure** – 9 states issue special licenses or certificates for telemedicine
- **Private Payer Laws** – 36 states and DC have private payer laws

Private Payer Laws

Coverage v. Payment



- Telemedicine coverage laws require health plans to cover services provided via telemedicine to the same extent the plan already covers the services if provided through an in-person visit.
 - “a health benefit plan that is issued, amended or renewed in this state shall not require in-person contact between a provider and a covered person for services provided through telehealth...” Colo. Stat. § 10-16-123(2)(a).



Private Payer Laws

Coverage v. Payment

- Telemedicine payment laws require health plans to reimburse providers for telemedicine services at the same or equivalent rate the health plan pays for services provided in-person.
 - “a carrier shall reimburse the treating participating provider for the diagnosis, consultation or treatment of the covered person delivered through telehealth on the same basis that the carrier is responsible for reimbursing that provider for the provision of the same service through in-person consultation or contact by that provider.” Colo. Stat. § 10-16-123(2)(b).
- 10 States have enacted strong telemedicine payment laws: Arkansas, Hawaii, Kentucky, Minnesota, Missouri, Montana, Nevada, New Mexico, Tennessee, and Virginia.



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Compliance and Fraud & Abuse Issues

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Adequate Technology

- Real-time audio-visual (gold standard) vs. store and forward, asynchronous
- Other state requirements
 - Certain security measures
- HIPAA compliance
 - Encryption requirement
 - FaceTime and Skype don't meet this requirement
 - Additional measures necessary to ensure security of transmissions?

Adequate Documentation

What does the state where the patient is located require?

- Telemedicine-specific informed consent
 - Including pros and cons of consultation via telemedicine
 - Back-up plan for if technology fails
- Special documentation regarding provision of services via telemedicine?
 - Requirement to document type of technology used?

Telemedicine-specific Policies and Procedures

Establish policies regarding:

- Back-up technology plan in the event of technology failure
- Referral of patient to local practitioner
- Required documentation
- Types of consultations that are appropriate for telemedicine
- QA processes for telemedicine exams

Fraud and Abuse Rules Governing Telemedicine

Federal Laws – Stark Law (42 U.S.C. § 1395nn)

- Prohibits a physician from referring Medicare or Medicaid patients for designated health services (“DHS”) to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies
- Prohibits the entity from submitting claims to Medicare or Medicaid for services resulting from a prohibited referral
- Strict liability statute – must meet all elements of an exception or the statute has been violated

Fraud and Abuse Rules Governing Telemedicine

Federal Laws – Stark Law (42 U.S.C. § 1395nn)

- Civil liability (not criminal)
- Potential Penalties
 - Overpayment/refund obligation
 - False Claims Act liability
 - Civil Monetary Penalties
 - Exclusion
- Government interpretation of the law is evolving
 - HHS vs. DOJ

Fraud and Abuse Rules Governing Telemedicine

Federal Laws – Stark Law (42 U.S.C. § 1395nn)

- Different exceptions for ownership and/or compensation arrangements; common exceptions in telemedicine include:
 - Employment relationships
 - Personal services arrangements
 - Space and equipment leasing arrangements
 - Fair market value (“FMV”) compensation arrangements
 - In-office ancillary services
 - Indirect compensation arrangements
 - Electronic prescribing and electronic health records items and services
- Exceptions generally require:
 - Signed, written agreement
 - Commercially reasonable, FMV compensation
 - Compensation does not reflect the volume/value of referrals

Fraud and Abuse Rules Governing Telemedicine

Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- Prohibits the knowing and willful offer or payment of or the solicitation or receipt of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients)



Fraud and Abuse Rules Governing Telemedicine

Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- “Remuneration”
 - Cash
 - Free equipment
 - Excessive compensation for medical directorships or consultancies or compensation where no legitimate services are provided
 - Provision of office assistance
 - Certain reimbursement services
 - Free rent
 - Expensive hotel stays, meals, travel, etc.



Fraud and Abuse Rules Governing Telemedicine

Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- Criminal law
- Applies to payers and recipients of kickbacks
- Each party's intent is a key element of their liability under the AKS – only “one purpose” needs to be to induce the purchase of a product or service or referrals
- Certain “safe harbor” protections (42 C.F.R. § 1001.952)
- Penalties include criminal (jail) and civil (monetary) penalties, and



Fraud and Abuse Rules Governing Telemedicine

Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- AKS Safe Harbors

- No liability if all elements of safe harbor are met
- BUT ... not an automatic violation if activities do not fit squarely in a safe harbor
- The closer an activity or arrangement comes to satisfying the requirements of a safe harbor, the safer the activity or arrangement

Fraud and Abuse Rules Governing Telemedicine

Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- Examples of common AKS Safe Harbors for Telemedicine:
 - *Bona fide* employment
 - Personal services contracts
 - Leases for space or equipment
 - Electronic prescribing and electronic health records items and services
- Common requirements for safe harbor protections:
 - Agreement covers all services to be provided by one party to another
 - Aggregate services provided do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose
 - Aggregate compensation, set in advance, consistent with FMV, not determined in a manner that takes into account the volume or value of referrals or other business generated

Fraud and Abuse Rules Governing Telemedicine

Federal Laws – False Claims Act (31 U.S.C. § 3729 *et seq.*)

– Prohibitions include:

- Knowingly submitting or causing to be submitted false or fraudulent claims
- Knowingly making, using, or causing to be made or used, false records or statements material to a false or fraudulent claim

– Penalties

- Treble damages
- Penalties currently \$11,181 - \$22,363 per false claim (as adjusted annually)

Fraud and Abuse Rules Governing Telemedicine

Federal Laws – False Claims Act (31 U.S.C. § 3729 *et seq.*)

- Examples of potential FCA violations related to telemedicine:
 - Referrals made in violation of Stark law or AKS
 - Claims submitted to Medicare where patient was not located at a qualifying originating site
 - Claims submitted to Tricare for prescriptions where doctors did not properly consult with the Tricare beneficiary (e.g., by consulting with the patient over the telephone rather than via a real-time A/V consult)

Fraud and Abuse Rules Governing Telemedicine

State Laws

- State law versions of:
 - Stark Law (prohibition against self-referral)
 - Anti-Kickback Statute (often including prohibitions against “fee splitting”)
 - False Claims Act
- Scope of state laws vary
 - Medicaid-only
 - Medicaid and commercial
 - Commercial
 - “All-payer”

Fraud and Abuse Rules Governing Telemedicine

State Laws

- Telemedicine laws
 - Establishing the requirements for the practice of medicine via telemedicine, including the requirements for a valid telemedicine visit in the state
- Corporate Practice of Medicine

Recent Enforcement Trends and Actions

- As federal dollars spent on telemedicine increase, enforcement actions will increase
- Unnecessary prescription of compounded drugs currently is a significant target (Tricare settlements)

Recent Enforcement Trends and Actions

DOJ Settlements

- Florida pharmacy settlements related to Tricare (2017)
 - Express Plus Pharmacy, LLC: \$170K
 - Related to the submission of claims to Tricare for compounded medications such as pain creams
 - Claims were not reimbursable because:
 - Not issued pursuant to a valid physician-patient relationship;
 - Prescriptions were issued after brief telephone calls, which violated applicable telemedicine laws;
 - Prescriptions were medically unnecessary; and
 - Prescriptions were tainted by kickbacks to marketers
 - Resolved allegations related to prescriptions from one physician

Recent Enforcement Trends and Actions

DOJ Settlements

- Florida pharmacy settlements related to Tricare (2018)
 - Healthy Meds Pharmacy Corp.: \$350K
 - Related to filling prescriptions in violation of Tricare’s policy on telemedicine, engaging in unsolicited calls to Tricare beneficiaries, and providing medically unnecessary compound medications to beneficiaries

Recent Enforcement Trends and Actions

OIG Review of Medicare Payments for Telehealth Services

- Added to OIG Work Plan in 2017
- OIG Report issued April 2018: “CMS Paid Practitioners For Telehealth Services That Did Not Meet Medicare Requirements”

Recent Enforcement Trends and Actions

OIG Review of Medicare Payments for Telehealth Services

– Findings:

- 31 out of 100 claims did not meet Medicare requirements
 - 24 claims unallowable because beneficiaries received services at non-rural originating sites
 - 7 claims billed by ineligible institutional providers
 - 3 claims for services to beneficiaries at unauthorized originating sites
 - 2 claims for services provided by unallowable means of communication
 - 1 claim for noncovered service
 - 1 claim for services provided by a physician located outside the U.S.

Recent Enforcement Trends and Actions

OIG Review of Medicare Payments for Telehealth Services

- Findings:
 - By extrapolation, improperly paid estimated \$3.7 million during the audit period (2014-2015)
 - Dollar amount is relatively low, but accounts for approximately 27% of all Medicare dollars spent on telehealth services during the audit period
 - Compare to 9.51% overall error rate for FY 2017 (July 1, 2015 – June 30, 2016)
- OIG recommended CMS:
 - Conduct periodic postpayment reviews of telehealth services
 - Work with Medicare contractors to implement required telehealth claim edits listed in Claims Processing Manual
 - Offer education and training to practitioners on Medicare telehealth requirements

Questions?



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