Compliance Issues in Telemedicine

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What is Telemedicine?

- The use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools, and other forms of telecommunications technology.” American Telemedicine Association.
- Telehealth & telemedicine often used interchangeably.
- Applicable laws/regulations define what constitutes “telemedicine” & what technologies captured.
- The “teleeverything” phenomenon

Telemedicine: 2 Types

- Asynchronous, Store & Forward Communications
  - Services that transmit medical data, x-rays, images, lab results to a distant site practitioner for later assessment
- Synchronous, Real-Time Communications
  - Provision of medical services through use of simultaneous, two-way communications between a patient/provider & distant site provider.
  - Interactive telecommunications devices
Telehealth Projections

InMedica predicts that it will be applied to 1.8 million patients worldwide by 2017, compared to 308,000 today. "Global Telemedicine Market - Growth, Trends & Forecasts (2015-2020)”, published by Mordor Intelligence estimates a global market for telemedicine in excess of $34B by the end of 2020.

Landscape for Telemedicine Innovation

Several emerging trends are setting the foundation for advancements in telemedicine:

- Healthcare providers are moving to reimbursement arrangements that require better health outcomes and lower overall costs.
- An ever-growing demand exists for innovative health information technology solutions and data-driven approaches, both from payors and patients.
- Policymakers have a serious concern about patient access to care and healthcare provider shortages.
- The global telemedicine and services market is expected to grow from US$21.1B in 2014 to US$86.7B in 2023.

How is Telemedicine Being Used
Telemedicine Use Cases

Barriers to Telemedicine
Before full benefits of telemedicine can be realized, several hurdles must be addressed:

- Public and Private Payor Reimbursement
- Conflicting State Laws/Regulations
- HIT Interoperability
- Clarity around modalities which comply with privacy and security legal requirements
- Flexibility for fraud and abuse and other laws which present barriers
- Malpractice liability/inconsistent insurance coverage

Regulatory Checklist

- State Telemedicine Laws including:
  - Medical Practice Act
  - Medical Board Policies or other Guidance
  - Attorney General Opinions
  - Standard of Care Law
  - Informed Consent Law
- State Licensure Laws including:
  - Medical Practice Act (Physicians)
  - Nursing Practice Act (e.g., Advanced Practice Registered Nurses, Clinical Nurse Specialists, Nurse Midwives)
  - Physician Assistant Practice Act (Physician Assistants)
  - State Psychology Practice Act (Psychologists)
  - State Social Worker Practice Act (Social Workers)
  - Applicable (e.g., Medical, Nursing, Psychology) Board Policies, Statements, Opinions
  - Attorney General Opinions
Regulatory Checklist

- Federal and State Laws Related to Prescribing including:
  - Medical Practice Act (or other applicable act depending on type of provider)
  - Pharmacy Practice Act
  - Medical (or other applicable professional board depending on type of provider) Board Policies or other Guidance
  - State Attorney General Opinions
  - Controlled Substance Act
  - Ryan Haight Online Pharmacy Consumer Protection Act of 2008
  - Drug Enforcement and Administration Enforcement Actions

Regulatory Checklist

- Federal (e.g., HIPAA/HITECH) and State Medical Record Retention Requirements
- Federal and State Privacy and Security Laws including:
  - HIPAA/HITECH
  - State sensitive information laws
- Federal Trade Commission Laws
- Federal (Medicare), State, or Accreditation Agency (e.g., The Joint Commission) Credentialing Requirements
- Federal Food and Drug Administration Requirements and Guidance (if mobile app constitutes a “device”)
- Federal Communications Commission Laws
- Federal and State Children’s Online Privacy Protection Laws (if services are provided to minors)

Regulatory Checklist

- Federal and State Fraud and Abuse Laws including:
  - Federal Anti-Kickback Statute and Office of Inspector General Advisory Opinions
  - Federal Physician Self-Referral Act (commonly known as “Stark Law”)
  - Federal False Claims Act
  - State mini-kickback, mini-Stark, and mini-false claims acts
  - State corporate practice of medicine prohibitions
  - State fee-splitting prohibitions
Regulatory Checklist

- Federal Medicare Telehealth Reimbursement Laws
  - Federal Medicare Site of Service Laws (e.g., Rural Health Clinics located in a qualifying area)
  - Federal Medicare Laws Regarding Charges to Beneficiaries
- State Medicaid Telehealth/Telemedicine Reimbursement Laws including:
  - State Medicaid Statutes and Regulations
  - State Insurance Statutes and Regulations
- Foreign and State Tax Laws

State Telemedicine Law Development

State Telemedicine Law Developments

- Throughout the 2016 legislative session, forty-four states introduced over 150 telehealth-related bills.
- States have implemented a wide variety of telehealth laws, ranging from very restrictive to extremely flexible in terms of what may be permitted as a valid telehealth encounter.
- In addition, states have differing policies and statutes which may affect the legality of a telehealth encounter:
  - Licensure
  - Prescribing
  - Valid physician-patient relationship
  - Reimbursement
  - Documentation
  - Consent, care of minors, end of life care
  - Standards of care and scope of practice
  - Insurance laws/regulations
State Telemedicine Law Developments

Examples: New York

New York: New York Board of Professional Medical Conduct

“A critical issue in telemedicine is determining the definition of a physician-patient relationship. [...] Some general statements are self-evident in their identification of a physician-patient relationship, and certain types of telecommunication are easily identifiable as not constituting a physician-patient relationship. [...] The committee concluded that the following statement of ACOG is a clear and practical guiding principal: “If a patient receives professional advice or treatment, even gratuitously, there is prima facie evidence that a physician-patient relationship exists.”

Examples: Texas

- On April 10, 2015 the Texas Medical Board voted to accept proposed rule changes to prohibit physicians licensed in Texas from prescribing medications without first establishing a defined “physician-patient relationship,” which includes establishing a diagnosis through an examination performed during a face-to-face encounter. Questions and answers exchanged through email, electronic text, or chat or telephonic evaluation of or consultation with a patient are inadequate to establish a doctor-patient relationship.

It is clear that the medical board acted only when Teladoc consultations became sufficiently numerous to be perceived as a competitive threat to brick-and-mortar physician practices.

- Jason Gorevic, Teladoc CEO

Dallas-based Teladoc, the first and largest U.S. telehealth company, filed a lawsuit against the Texas Medical Board, claiming the April 2015 rule changes violated federal antitrust laws.

Teladoc employs board certified physicians to consult with registered patients and dispense medical advice over the phone. When deemed appropriate, a Teladoc physician can prescribe certain medications.

The Texas Medical Board’s proposed rule would inhibit Teladoc physicians from prescribing medications where the physician had not first established a diagnosis through an examination performed during a face-to-face encounter.


- In May 2015, U.S. District Court Judge Robert Pitman issued a temporary injunction to postpone the rule’s implementation until the litigation is resolved.
- In December 2015, a federal trial court denied the Texas Medical Board’s motion to dismiss the lawsuit because the board failed to satisfy the elements for the state-action immunity doctrine.
- In June 2016, the Texas Medical Board appealed that decision to the U.S. Court of Appeals for the 5th Circuit, arguing that it has been charged by the state with regulating the practice of medicine and that it is subject to the state’s active supervision.
- Teladoc is expected to file a brief in August.

Licensure & Telemedicine

[Image of a stethoscope on a clipboard]
Licensure & Telemedicine

- Historically, because of patient safety concerns, physicians practicing within a state must obtain a full license to practice, with limited exceptions.
- Process to obtain licensure varies from state to state and is dictated by each state’s Medical Practice Act.
- Each medical license may take upwards of two months, from the date of initial application to finally granting the license, and state licensing fees range from $200–$1,000.
- 9 states – LA, ME, MN, NM, NV, OH, OR, TN, TX have special telehealth licenses.

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Licensure & Telemedicine

Federation of State Medical Board (FSMB) Interstate Medical Licensure Compact

- Introduced in 2015
- Under the new proposed system, participating state medical boards would retain their licensing and disciplinary authority, but would agree to share information and processes essential to the licensing and regulation of physicians who practice across state borders.
- Participation in the Compact would be voluntary, for both states and physicians.

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Licensure & Telemedicine

Interstate Medical Licensure Compact

- Introduces the concept of reciprocity in medical licensing across states.
- Focuses on the seamless transfer of licenses and credits for medical education and training.
- Aims to reduce barriers to patient care and improve access to medical services.
- Provides a framework for states to work together in promoting public health and improving patient safety.
Additional FSMB Work

In addition to the Interstate Medical Licensure Compact, in April 2014, the Federation of State Medical Boards released the “Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Telemedicine.”

• Requires documentation for any telemedicine services provided.
• Requires physicians be licensed in accordance with state laws and medical practice.
• Stresses the importance of continuity of care.

Standards of Care

• The AMA has been active and made several overall policy recommendations:
  - Telemedicine services should be covered and paid for
  - A valid physician-patient relationship must be established prior to providing telemedicine services
    • Valid relationship established through a face-to-face examination, a consultation with another physician who has an on-going patient-physician relationship with the patient and agrees to supervise patient’s care, or meeting standards of establishing a patient-physician relationship included as part of evidenced-based clinical practice guidelines on telemedicine.
  - Must abide by state licensure and medical practice laws
    • Must be licensed in state where patient receives services
  - Grant patients a choice of providers
  - Inform patients of the provider’s credentials

Standards of Care

- Standards and scope of telemedicine services should be consistent with in-person services
- Ensure transparency in delivering services
- Collect the patient’s medical history as part of providing services
- Document provision of telemedicine services
- Coordinate the patient’s care with the patients’ medical home and/or existing treating physicians
  • This includes, at a minimum, identifying the patient’s existing medical home and treating physicians and providing such physicians with a copy of the patient’s record
- Establish protocols for referring patients for emergency services
- Compliance with evidence-based practice guidelines
• State Laws
• Insurance Coverage
Prescribing Issues

- Mirrors legal issues inherent to telemedicine
- Compliance with state/federal prescribing & dispensing laws
  - Licensure of pharmacy & pharmacist (particularly if patient in different state)
- Face-to-Face Prescribing Requirement:
  - Varies by State
  - Federal Law: Ryan Haight Online Pharmacy Consumer Protection Act of 2008 makes it illegal for practitioner to issue prescription for controlled substance based solely on an online evaluation of the patient, but it exempts providers engaged in the "practice of telemedicine" from this requirement.

  
  "Practice of telemedicine" — "the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, using (an asynchronous, store-and-forward telecommunications system that satisfies federal regulations)."

Telemedicine Privacy & Security

- HIPAA applies to telemedicine encounters and all requisite safeguards must be in place.
- Compliance can be complicated because now documentation is in a variety of forms (video, audio, image), not just as part of a paper or electronic record.
- Many state laws on telemedicine specify the extent to which non-paper communications must be recorded and stored in the medical record.
- Risk assessments may need to be revisited, as telemedicine models can draw in additional persons who may access personal health information, and additional security risks can arise.

Telemedicine Privacy & Security

- Providers need to be cautious about products that claim to be "HIPAA-compliant"; compliance requires a number of controls and protocols, at a minimum, and cannot be certified by the telemedicine modality alone.
- Remember that the January 25, 2013 CMS final HIPAA Omnibus rule extended the reach of HIPAA (RIN 0945–AA03).
- Other modalities were not expressly created to provide functionality for telemedicine, and do not claim to be HIPAA-compliant, yet they are being used by providers.
- Remember that providers can shoulder risk here, just as they face risk from medical licensure board actions.
HIPAA/HITECH Issues

- Providers are responsible for protecting the confidentiality, integrity, and security of ePHI stored in EHR in accordance with HIPAA, the HITECH Act, and non-conflicting state privacy laws and regulations.
- In selecting vendor must:
  - Ensure vendor is capable of achieving HIPAA compliance
  - Negotiate liability for breaches & managing the breach disclosure process (operationally & financially)

HIPAA/HITECH Issues

- HIPAA/HITECH compliance
  - Cannot rely on vendor to achieve HIPAA compliance
    - But must verify technology capable of HIPAA compliance
  - Data transmissions between devices & provider locations invite greater opportunity for HIPAA breaches
    - HITECH Act defines “breach” at 42 U.S.C. 17921(1) as “the unauthorized acquisition, access, use or disclosure of protected health information which comprises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information.”

HIT Interoperability

- Electronic Health Record (EHR) systems are typically not interoperable with one another, nor are they interoperable with many device or modalities, making reporting of patient information difficult.
- Hypothetical: Patient’s primary care provider (PCP) uses EHR A. Patient’s PCP is unavailable after hours, so Patient sees telehealth provider (TP), who uses EHR B. The information about Patient’s visit with TP cannot seamlessly be integrated from EHR A to EHR B, which may jeopardize the patient record.
- Federal lawmakers have been crafting legislation to address EHR interoperability issues (for example, in the 21st Century Cures legislation), but implications for telehealth are still unclear
**FTC Regulatory Compliance**

- The Federal Trade Commission ("FTC") is directed, under Section 5 of the FTC Act, 15 U.S.C. § 45, to prevent "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce."
- FTC regulates truth in advertising & data privacy for mobile medical apps
  - FTC v. Lasarow – FTC charged Avrom Lasarow & his company (L Health) with false advertising of its Mole Detective Apps. FTC said company "deceptively claimed the apps accurately analyzed melanoma risk and could assess such risks in early stages". Case settled.
- FTC Health Breach Notification Rule (16 C.F.R. Part 318) (applies to non-HIPAA governed entities)
  - If a business is a vendor of PHR or a PHR-related entity and experiences an unauthorized acquisition of PHR-identifiable health information that is unsecured and in a personal health record, then it must, within specified time periods, provide notice of the breach that includes specified information to each affected person who is a citizen or resident of the United States, the FTC, and in some cases the media.

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**Credentialing – Medicare COP**

- Credentialing presents administrative complications when implementing telemedicine unless provisions allow for services through originating- and distant-site providers.
- On May 5, 2011, CMS revised its telemedicine credentialing policy in final rule CMS-3227-F.

- § 482.22(a)(3)
  - Condition of participation: Medical staff provides that when telemedicine services are furnished to the hospital’s patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose...to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital’s governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:
    1. The distant-site hospital providing the telemedicine services was another Medicare participating hospital;
    2. The individual distant-site physician or practitioner was privileged at the distant-site hospital providing telemedicine services, and that this distant-site hospital provides a current list of the physician’s or practitioner’s privileges;
    3. The individual distant-site physician or practitioner held a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located; and
    4. With respect to a distant-site physician or practitioner granted privileges by the hospital, the originating-site hospital had evidence of an internal review of the distant-site physician’s or practitioner’s performance under these telemedicine privileges and sent the distant-site hospital this information for use in its periodic appraisal of the individual distant-site physician or practitioner.
Credentialing – TJC

• The Joint Commission (TJC) also revised its standards in regard to telemedicine credentialing in 2011 (Standard LD.04.03.09).

• Under the TJC’s current standard, a practitioner with credentials in the originating site may provide services to patients at the distant site, as long as the practitioner is licensed in the state where patient receives services, and as long as other due diligence is performed, such as making sure services do not go beyond credentials in the originating site.

Credentialing – TJC Standard LD.04.03.09

• Clinical leaders get to provide advice re. services to be provided via contract
• Hospital has written description of nature and scope of services to be provided
• Leaders monitor performance via expectations of performance
• Communicate those expectations of performance to provider
• Leaders evaluate performance via expectations of performance
• Leaders require remedial measures when expectations of performance are not met

Credentialing – TJC Standard LD.04.03.09

• For hospitals that use TJC accreditation for deemed status purpose, there must be a written agreement between the originating site with the distant site that specifies:
  – The distant site is a contractor of services to the hospital
  – The governing body of the distant site is responsible for having a process that is consistent with the credentialing and privileging requirements in the MS Chapter
  – The distant site furnishes services in a manner that permits the originating site to be in compliance with Medicare COP
  – The governing body of the originating site grants privileges to a distant site practitioner based on the originating site’s medical staff recommendations, which rely on information provided by the distant site.
FTC Releases mHealth App Guidance

- On April 5, 2016, the FTC released new guidance for developers of mobile health applications to help app developers comply with the FTC Act.
- The new guidance focuses on:
  - Minimizing Data
  - Limiting Access and Permissions
  - Authentications
  - Considering the Mobile Ecosystem
  - Implementing Security by Design
  - Avoiding Reinventing the Wheel
  - Cross-referencing other Applicable Laws
- The FTC has also developed an interactive web-based tool to allow developers to respond to various fact-based questions to determine which of these federal laws they are required to follow.

Does the FDA Regulate the App?

Mobile App. vs. Mobile Medical App.

- A “mobile application” or “mobile app” is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server.
- “Mobile medical application” is a mobile app that meets the definition of device in Section 201(h) of the FD&C Act and either is intended:
  1. To be used as an accessory to a regulated medical device; or
  2. To transform a mobile platform into a regulated medical device.

FDA Regulation

The FDA defines a ‘mobile medical app’ as a mobile app that is intended to either:

- Be used as an accessory to a regulated medical device; or
- Transform a mobile platform into a regulated medical device.

What is a regulated medical device? The FDA guidance states that:

- When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body of man, the mobile app is a device.
Mobile Apps & FDA Regulation

- Some mobile apps will be subject to FDA enforcement discretion, rather than regulated. The FDA provides an appendix with examples of those apps – see http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf#page=23

In February 2015, FDA released updated nonbinding guidance on mobile medical apps.

FDA Compliance

- FDA Regulatory Compliance
  - FDA applies its regulatory oversight discriminately to regulate mobile apps based on their intended functionality and relative risk to the public, not based on the technology or software platform.
  - FDA believes "many mobile apps are not medical devices (meaning such mobile apps do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”)) to authorize the FDA’s regulation of them; while, some mobile applications may meet the definition of a ‘medical device’ but pose an insufficient risk of public harm to merit enforcing the FD&C Act over these."
Does the FDA Regulate the App?

- **Mobile Apps that FDA regulates:**
  - Apps that transform the mobile platform into a regulated medical device by using attachments, display screens, sensors or include functionalities similar to currently regulated medical devices.
  - Apps that perform patient-specific analysis and provide patient-specific diagnoses.
  - Apps that are extensions of medical devices (control the device or used in active patient monitoring or analyzing medical device data).

- **Mobile Apps that FDA does NOT intend to regulate:**
  - Apps intended to provide access to medical textbooks, reference materials.
  - Apps intended for providers to use as educational tools (initial medical training or reinforce past training).
  - Apps intended for general patient education & facilitate access to commonly used reference materials (filters info based on patient characteristics) to increase patient awareness, education, empowerment.
  - Apps that automate general office functions (reminders, appointment-making).

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Does the FDA Regulate the App?

- **The Grey Zone (FDA will exercise its discretion to regulate the following):**
  - Apps that provide or facilitate supplemental clinical care (by coaching or prompting patients to manage their health in daily environment).
  - Apps that provide simple tools to organize & track health info.
  - Apps that provide easy access to info on patient’s health condition or treatments.
  - Apps marketed to help patients document, show, or communicate potential medical conditions to providers.

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FCC Regulatory Compliance

- FCC regulates mHealth technologies (mobile apps, mobile medical apps, etc.) as communication devices, rather than medical devices.
- FCC allocated spectrum exclusively for use by mobile body area networks (MBANs) & other wireless remote monitoring technologies (mobile medical apps). The spectrum forms a personal wireless network in which data from body sensors can be aggregated into central device & transmitted in real time at rates much faster & more reliable than typical transmission.
- Reduces risk of data being compromised.
COPPA Compliance

- Children's Online Privacy Protection Act of 1998 ("COPPA") requires FTC to enforce regulations concerning children's online privacy
- Applies to:
  - Operators of commercial websites & online services (mobile apps) directed to children under 13 that collect, use, disclose personal info about children
  - Operators of general audience websites or online services who have actual knowledge that they are collecting, using, or disclosing personal info collected from children under 13
  - Websites, online services that have actual knowledge that they are collecting personal information from users of another website or online service that was directed to children under 13.

COPPA Compliance

- Operators covered by COPPA Rule must:
  - Post clear & comprehensive online privacy policy describing their information practices for personal info collected online from children
  - Provide direct notice to parents & obtain verifiable parental consent before collecting personal info from children
  - Give parents choice to consent to operator's collection/internal use of info or prohibit disclosure to third parties (unless disclosure integral to the site or service)
  - Provide parental access to collected info or delete it
  - Give parents opportunity to prevent further use/disclosure
  - Maintain confidentiality, security, & integrity of info collected
  - Retain personal info for only as long as necessary to fulfill the purpose for which it was collected & delete it using reasonable measures to protect against unauthorized use/disclosure

Federal Fraud Statutes

- Generally includes AKS, Stark, FCA, and CMP
- Raises an issue for telemedicine arrangements:
  - Service Agreement
  - Vendor Agreements
  - Usually fall in personal services & management contracts
- In June 2015, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) issued a Fraud Alert cautioning healthcare providers, and specifically physicians, to “…carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering into them.”
Anti-Kickback Statute

- Anyone
- Gives or receives
- Anything of value
- In return for referral (ordering, arranging for, recommending)
- Items or services covered by Medicare, Medicaid or CHAMPUS

**Statute:** 42 U.S.C. § 1320a-7b

**Regulations:** 42 C.F.R. § 1001.952

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Penalties

- **Criminal**
  - Fine ($2,500 +)
  - Jail (5 year +)
- **Civil**
  - $5,000 or $10,000 per claim
  - Plus treble damages
  - $5,000 or $10,000 per claim
  - Plus treble damages
- Exclusion from Medicare/Medicaid
- Enforced by the Office of the Inspector General (“OIG”) and the Department of Justice (“DOJ”)
Physician Self-Referral Law
aka Stark I, II, and III

A Physician may not refer patients covered by Medicare Part B (and to some extent Medicaid) for “Designated Health Services” to an entity with which the physician has a financial relationship.

Statute: 42 U.S.C. § 1395nn
Regulations: 42 C.F.R. § 411.351

Stark

Designated Health Services
- Clinical laboratory services
- Physical therapy, occupational therapy, and speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services
**Designated Health Services**

- There is also a list of designated health services that lists “DHS” by CPT Codes
- The list is published by CMS
- The list is updated in the Federal Register periodically as changes occur

The list can be accessed at the CMS website: [www.cms.hhs.gov/PhysicianSelfReferral/](http://www.cms.hhs.gov/PhysicianSelfReferral/)

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**Penalties**

- **Civil**
  - $15,000 per claim
  - Assessment 3x amount of claim
- Nonpayment or recovery
- Exclusion from Medicare/Medicaid
- Denial of payment
- 60 day refund
- Enforced by the CMS, although DOJ adjudicates false claims arising from violations of the Stark Law.

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**Penalties**

*For the Physician:*
- Referral should not have been made for DHS Services
- Potential False Claims Act Liability (new focus on Physicians)

*For the Entity:*
- Disgorge Medicare payment for the DHS
- Payment of civil monetary penalties of up to $15k for each claim that a person “knows or should know” was made in violation of the Stark Law
- Exclusion from Federal/state health care payor programs
- CMPs for attempting to circumvent the Stark Law of up to $100k for each circumvention scheme
**Guidance Regarding Stark**

- CMS expects attorneys to be well-versed in Stark I, II, and III.
- Best tutorial is the commentary to each set of regulations:
- Sign up for [http://www.cms.hhs.gov/AboutWebsite/EmailUpdates/list.asp](http://www.cms.hhs.gov/AboutWebsite/EmailUpdates/list.asp)

**Public and Private Reimbursement**

- To date, federal and state reimbursement laws and regulations governing the reimbursement for and coverage of telemedicine services have not allowed for the full promise of telemedicine to be realized.
- Medicare, Medicaid, and private payers have different policies governing reimbursement for and coverage of telemedicine services.
- The use of telemedicine services is further complicated by conflicting state laws and policies.

**Reimbursement - Medicare**
Reimbursement - Medicare

- Medicare only covers telemedicine services offered to patients under certain limited circumstances.
- The originating site must be located in a county outside of a Metropolitan Statistical Area (MSA), a Health Professional Shortage Area located outside of an MSA, or in a rural census tract, as determined by the Office of Rural Health Policy within the Health Resources and Services Administration.
- Finally, as a condition of payment, the provider must use an interactive audio and video telecommunications system that permits real-time communication between the provider, the distant site, and the beneficiary.

Telemedicine: Reimbursement

- Medicare Conditions of Payment for Telehealth Services (42 C.F.R. §410.78):
  1. Qualifying distant site practitioner (licensed MD, PA, APRN, CNS)
  2. Distant site practitioner authorized by state scope of practice laws/regulations to perform services offered via telehealth
  3. Patient located at a qualifying originating site:
     - Health Professional Shortage Area (“HPSA”) outside of a Metropolitan Statistical Area (MSA)
     - HPSA in rural census tract (defined by Office of Rural Health Policy)
     - County not in an MSA
  4. Medical Exam controlled by the distant site practitioner
  5. CMS authorized reimbursement for those services

Reimbursement - Medicare

- CMS’s 2016 Physician Fee Schedule (PFS) Final Rule (FR) added the following to the list of services that can be furnished under the Medicare telehealth benefit:
  - ESRD-related services
  - Advanced care planning
  - Telehealth consultations for a patient who requires clinical care services
- CMS’ 2015 physician payment fee schedule final rule added the following services to the list of services that can be furnished under the Medicare telehealth benefit:
  - Psychoanalysis
  - Family Psychotherapy
  - Prolonged evaluation and management services
- CMS’ new “Next Generation ACO Model” requires that provider participants offer telehealth services. Viewed by stakeholders as an acknowledgement by CMS of the value of telehealth in alternative payment models.
- Starting in CY2017, CMS is proposing to add several services to the list of telehealth services eligible for Medicare reimbursement, including:
  - ESRD Related Services
  - Advanced Care Planning Services
  - Critical Care Consultations Furnished via Telehealth
  - MACRA
Telehealth Coding

Proposals Approved at February 2016 CPT Editorial Panel Meeting

1) Telehealth Services Modifier: Modifier appended to identify and allow reporting of telehealth service variations on traditional face-to-face services
2) Listing of CPT codes currently covered by payors for telehealth services

Telehealth Coding

In The Works

To be voted on at May 2016 CPT Editorial Panel Meeting:

1) Asynchronous Modifier: Modifier appended to identify and allow reporting telehealth services rendered via asynchronous (store-and-forward) telecommunication systems
2) Synchronous Modifier definitions

Reimbursement – Medicaid

Medicaid.gov

Medicaid.gov
Reimbursement – Medicaid

- Differs from state to state.
- States must still satisfy federal requirements of “efficiency, economy and quality of care.”
- Once the state meets the necessary federal requirements, the state may choose:
  - whether to cover telemedicine services;
  - the types of telemedicine services that it will cover;
  - how telemedicine will be provided and covered; and
  - locations within the state where these services may be provided.
- 48 state Medicaid programs offer some type of coverage
- 32 states + D.C. require private insurance plans to cover telemedicine services

48 state Medicaid programs offer some type of coverage
32 states + D.C. require private insurance plans to cover telemedicine services

According to informal guidance issued by CMS on the Medicaid.gov website, Medicaid is currently encouraging states to use the flexibility “inherent in federal law” to create payment methodologies for services that use telemedicine technology.

Almost all states (49+ District of Columbia) provide some coverage for telehealth services
19 states allow fewer than 9 provider types to receive reimbursement for telehealth; 4 states allow reimbursement only for physicians; 15 states and D.C. do not specify the type of provider
24 states and D.C. do not specify a patient setting or location as a condition of payment
32 states and D.C. also have required private insurance plans to cover telemedicine services
24 states include telemedicine services in their state employee health plans

http://www.ncsl.org/research/health/state-coverage-for-tel ehealth-services.aspx
Questions?

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