Compliance Issues in Telemedicine

HCCA Atlanta Regional Conference
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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

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Telemedicine: Two 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

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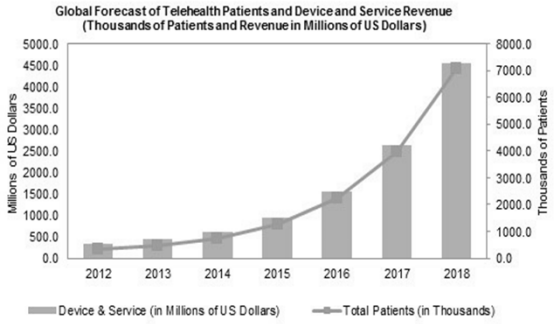
Telehealth Projections



Source: IHS Technology, January 2014

- 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

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Landscape for Telemedicine Innovation

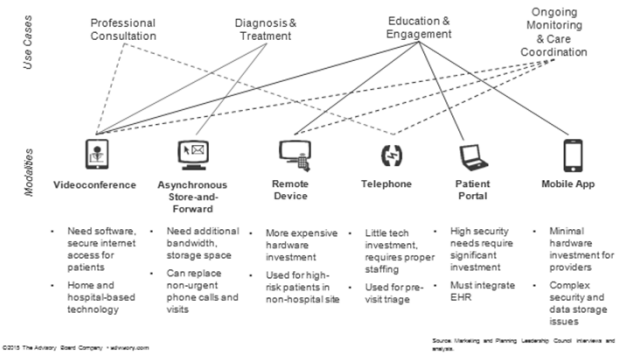
Several emerging trends are setting the foundation for advancements in telemedicine:

- 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$86.7 B in 2023.

How is Telemedicine Being Used

Telemedicine Use Cases

Use Cases May Be Achieved Across Multiple Modalities



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

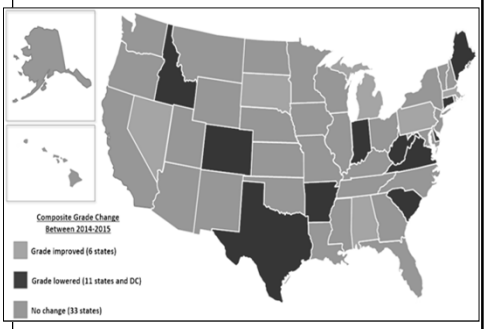
- Throughout the 2016 legislative session, forty-four states introduced over 150 telehealth-related bills.
- States have implemented a wide variety of telehealth laws, ranging from very restrictive to extremely flexible in terms of what may be permitted as a valid telehealth encounter.
- In addition, 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

State Telemedicine Law Composite Grade Score, 2015

Source: American Telemedicine Association 2015

State Telemedicine Law Composite Grade Score Change, 2014-2015



Source: American Telemedicine Association 2016

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.

Teladoc, Inc. v. Tex. Med. Bd.

"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.

Teladoc, Inc. v. Tex. Med. Bd.

- 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

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.

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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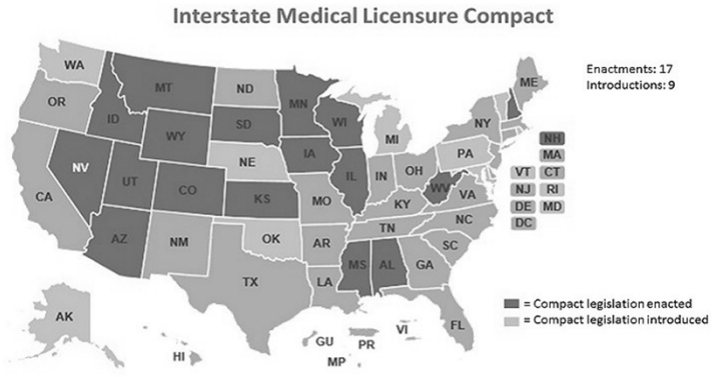
Licensure & Telemedicine



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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.
    - "[P]ractice 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 risk 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.*

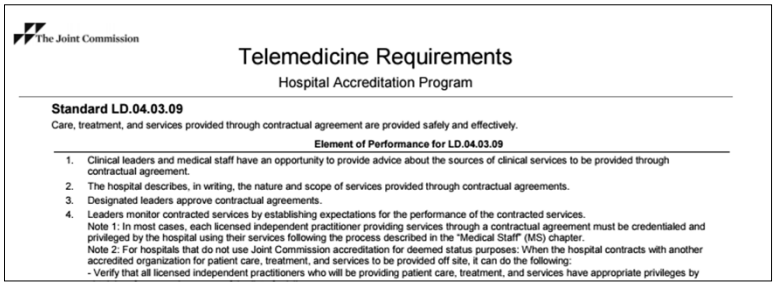
Credentialing – Medicare COP

- 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:

Credentialing – Medicare COP

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

Telemedicine Requirements

Hospital Accreditation Program

Standard LD.04.03.09

Care, treatment, and services provided through contractual agreement are provided safely and effectively.

Element of Performance for LD.04.03.09

1. Clinical leaders and medical staff have an opportunity to provide advice about the sources of clinical services to be provided through contractual agreement.
2. The hospital describes, in writing, the nature and scope of services provided through contractual agreements.
3. Designated leaders approve contractual agreements.
4. Leaders monitor contracted services by establishing expectations for the performance of the contracted services.
   Note 1: In most cases, each licensed independent practitioner providing services through a contractual agreement must be credentialed and privileged by the hospital using their services following the process described in the "Medical Staff" (MS) chapter.
   Note 2: For hospitals that do not use Joint Commission accreditation for deemed status purposes: When the hospital contracts with another accredited organization for patient care, treatment, and services to be provided off site, it can do the following:
   - Verify that all licensed independent practitioners who will be providing patient care, treatment, and services have appropriate privileges by

- 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
  - Innovating Communications with Users
  - 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.

See Lynn Scott & Sidney Welch, *The FTC Releases Guidance for mHealth App Developers*, 3 EHEALTH LAW & POL'Y 6 (2016). Worksite Doc. No. = 53532907.1

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:

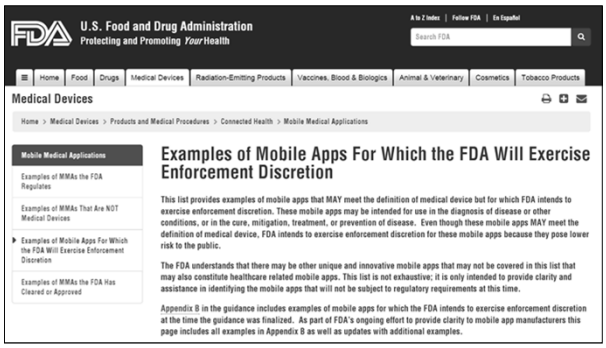
- Be used as an accessory to a regulated medical device; or
- Transform a mobile platform into a regulated medical device.

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 any function of the body of man, the mobile app is a device.*

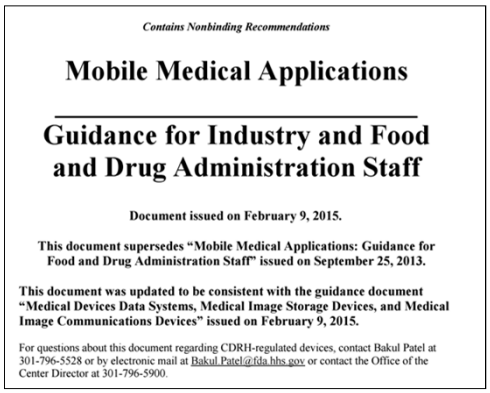
Mobile Apps & FDA Regulation

- 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*



FDA Regulation

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


Contains Nonbinding Recommendations

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on February 9, 2015.

This document supersedes "Mobile Medical Applications: Guidance for Food and Drug Administration Staff" issued on September 25, 2013.

This document was updated to be consistent with the guidance document "Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices" issued on February 9, 2015.

For questions about this document regarding CDRH-regulated devices, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov or contact the Office of the Center Director at 301-796-5900.

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 "[m]any 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 diagnosis
  - 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)

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

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."

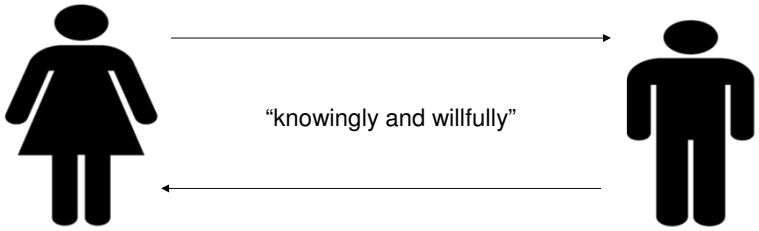
Anti-Kickback Statute

- 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

Anti-Kickback Statute



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")

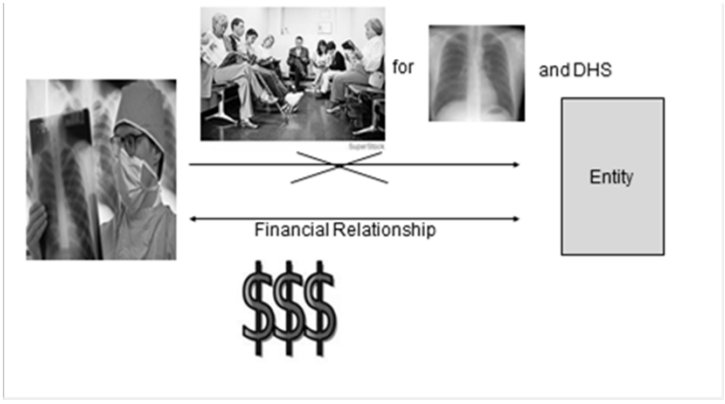
Physician Self-Referral Law aka Stark I, II, and III

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/

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.

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

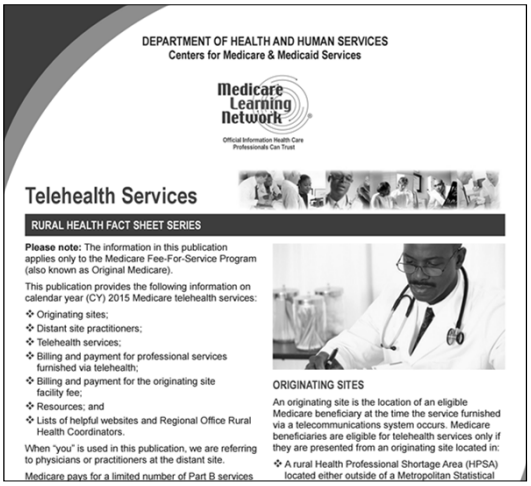
Guidance Regarding Stark

- CMS expects attorneys to be well-versed in Stark I, II, and III
- Best tutorial is the commentary to each set of regulations
  - http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/66FR856.pdf
  - http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/69FR16054.pdf
  - http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-4252.pdf
- Sign up for 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



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Medicare Learning Network
Official Information Health Care Professionals Can Trust

Telehealth Services

RURAL HEALTH FACT SHEET SERIES

Please note: The information in this publication applies only to the Medicare Fee-For-Service Program (also known as Original Medicare).

This publication provides the following information on calendar year (CY) 2015 Medicare telehealth services:

- Originating sites;
- Distant site practitioners;
- Telehealth services;
- Billing and payment for professional services furnished via telehealth;
- Billing and payment for the originating site facility fee;
- Resources; and
- Lists of helpful websites and Regional Office Rural Health Coordinators.

When "you" is used in this publication, we are referring to physicians or practitioners at the distant site.

Medicare pays for a limited number of Part B services

ORIGINATING SITES

An originating site is the location of an eligible Medicare beneficiary at the time the service furnished via a telecommunications system occurs. Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in:

- A rural Health Professional Shortage Area (HPSA) located either outside of a Metropolitan Statistical

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 licensure 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 Coverage & Reimbursement

CY 2016 Medicare Telehealth Services

Service	Healthcare Common Procedure Coding System (HCPCS)/CPT Code
Telehealth consultations, emergency department or initial inpatient	HCPCS codes G0425–G0427
Follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals or SNFs	HCPCS codes G0406–G0408
Office or other outpatient visits	CPT codes 99201–99215
Subsequent hospital care services, with the limitation of 1 telehealth visit every 3 days	CPT codes 99231–99233
Subsequent nursing facility care services, with the limitation of 1 telehealth visit every 30 days	CPT codes 99307–99310
Individual and group kidney disease education services	HCPCS codes G0420 and G0421
Individual and group diabetes self-management training services, with a minimum of 1 hour of in-person instruction to be furnished in the initial year training period to ensure effective injection training	HCPCS codes G0108 and G0109
Individual and group health and behavior assessment and intervention	CPT codes 96150–96154
Individual psychotherapy	CPT codes 90832–90834 and 90836–90838
Telehealth Pharmacologic Management	HCPCS code G0459
Psychiatric diagnostic interview examination	CPT codes 90791 and 90792
End-Stage Renal Disease (ESRD)-related services included in the monthly capitation payment	CPT codes 90951, 90952, 90954, 90955, 90957, 90958, 90960, and 90961
End-Stage Renal Disease (ESRD)-related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents (effective for services furnished on and after January 1, 2016)	CPT code 90963
End-Stage Renal Disease (ESRD)-related services for home dialysis per full month, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents (effective for services furnished on and after January 1, 2016)	CPT code 90964
End-Stage Renal Disease (ESRD)-related services for home dialysis per full month, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents (effective for services furnished on and after January 1, 2016)	CPT code 90965
End-Stage Renal Disease (ESRD)-related services for home dialysis per full month, for patients 20 years of age and older (effective for services furnished on and after January 1, 2016)	CPT code 90966
Individual and group medical nutrition therapy	HCPCS code G0270 and CPT codes 97802–97804
Neurobehavioral status examination	CPT code 96116
Smoking cessation services	HCPCS codes G0436 and G0437 and CPT codes 99406 and 99407
Alcohol and/or substance (other than tobacco) abuse structured assessment and intervention services	HCPCS codes G0396 and G0397
Annual alcohol misuse screening, 15 minutes	HCPCS code G0442
Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes	HCPCS code G0443

CY 2016 Medicare Telehealth Services (cont.)

Service	Healthcare Common Procedure Coding System (HCPCS)/CPT Code
Annual depression screening, 15 minutes	HCPCS code G0444
High-intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes	HCPCS code G0445
Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes	HCPCS code G0446
Face-to-face behavioral counseling for obesity, 15 minutes	HCPCS code G0447
Transitional care management services with moderate medical decision complexity (face-to-face visit within 14 days of discharge)	CPT code 99495
Transitional care management services with high medical decision complexity (face-to-face visit within 7 days of discharge)	CPT code 99496
Psychoanalysis	CPT codes 90845
Family psychotherapy (without the patient present)	CPT code 90846
Family psychotherapy (conjoint psychotherapy) (with patient present)	CPT code 90847
Prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour	CPT code 99354
Prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes	CPT code 99355
Prolonged service in the inpatient or observation setting requiring unitfloor time beyond the usual service; first hour (list separately in addition to code for inpatient evaluation and management service) (effective for services furnished on and after January 1, 2016)	CPT code 99356
Prolonged service in the inpatient or observation setting requiring unitfloor time beyond the usual service; each additional 30 minutes (list separately in addition to code for prolonged service) (effective for services furnished on and after January 1, 2016)	CPT code 99357
Annual Wellness Visit, includes a personalized prevention plan of service (PPPS) first visit	HCPCS code G0438
Annual Wellness Visit, includes a personalized prevention plan of service (PPPS) subsequent visit	HCPCS code G0439

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Telehealth Coverage & Reimbursement

CONNECT for Health Act

Introduced by Senators Schatz, Wicker, Cochran, Cardin, Thune, and Warner and Representatives Black, Welch, and Harper

Promoting cost savings & quality care in Medicare through telehealth and remote patient monitoring

- The CONNECT for Health Act would **expand the use of telehealth and remote patient monitoring services in Medicare**, toward the goal of cost savings and quality care.
- Telehealth is the use of telecommunications technologies to deliver health care, health information, or health education at a distance. Clinical uses include video conferencing, remote patient monitoring (RPM) services (use of telecommunications tools to monitor high-risk patients at home), and store-and-forward technologies (asynchronous transfer of medical data for analysis and care).
- Numerous studies on telehealth and RPM have shown benefits in quality care and cost savings.[1]
- Provisions in current statute (42 U.S.C. 1834(m)) constrain telehealth reimbursement by:
  - **Originating site restrictions** – the patient may only be located at certain clinical sites;
  - **Geographic limitations** – the patient may only be located in certain rural areas;
  - **Restrictions on store-and-forward technologies** – only permitted in Alaska and Hawaii;
  - **Limitations on distant site providers** – only Medicare-defined "physicians" and "practitioners" may provide telehealth services, but not, for example, physical or occupational therapists; and
  - **Limitations on covered codes** –CMS must define reimbursable telehealth codes.

CONNECT for Health Act solutions

- The CONNECT for Health Act would:
  - Create a **bridge program** to help providers transition to the goals of the Medicare Access and CHIP Reauthorization Act (MACRA) and the Merit-based Incentive Payment System (MIPS) through using telehealth and RPM without most of the aforementioned 1834(m) restrictions;
  - Allow telehealth and RPM to be used by qualifying participants in **alternative payment models**, without most of the aforementioned 1834(m) restrictions;
  - Permit the use of **remote patient monitoring** for certain patients with chronic conditions;
  - Allow, as originating sites, **telestroke evaluation and management sites; Native American health service facilities;** and **dialysis facilities** for home dialysis patients in certain cases;
  - Permit further telehealth and RPM in **community health centers** and **rural health clinics;**
  - Allow telehealth and RPM to be **basic benefits in Medicare Advantage**, without most of the aforementioned 1834(m) restrictions; and
  - Clarify that the provision of telehealth or RPM technologies made under Medicare by a health care provider for the purpose of furnishing these services shall not be considered "remuneration."

Potential for cost savings

- The bill includes requirements regarding cost containment, quality measures, and data collection.
- An Avalere analysis[2] of three of the major provisions of the bill (first three bullets above) showed **$1.8 billion in savings over 10 years.**

Endorsements noted on back. Please contact Aimee Grace (aimee_grace@schatz.senate.gov) for questions.

[1] http://ccbcea.org/research-catalogues
[2] Avalere Health. Estimated Federal Impact of Proposed Policy Changes to Expand Medicare Reimbursement of Telehealth and Remote Patient Monitoring. January 11, 2016.

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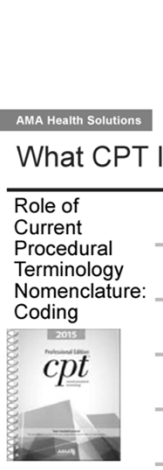
Telehealth Coding

AMA Health Solutions

What CPT Is

Role of Current Procedural Terminology Nomenclature: Coding	CPT is a listing of descriptive terms and identifying codes for reporting medical services and procedures
	The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, providing a means for harmonized communication among physicians and others in the healthcare ecosystem
	CPT descriptive terms and identifying codes currently serve as the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs, and for administrative management
	Providers, payers, clearing houses mandated use
	Technology neutral



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Telehealth Coding

AMA Health Solutions

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

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Telehealth Coding

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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

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Reimbursement – Medicaid

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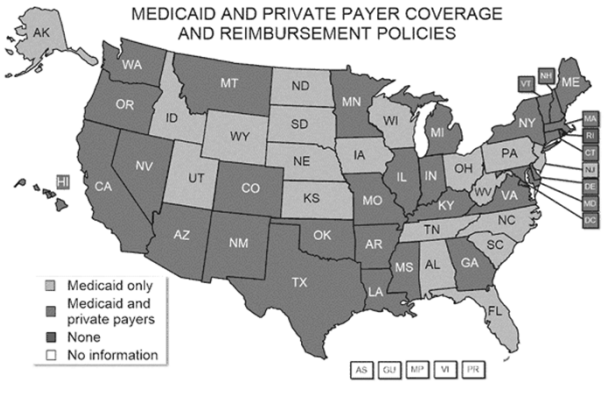
Reimbursement – Medicaid

- 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

Medicaid Coverage



http://www.ncsl.org/research/health/state-coverage-for-telehealth-services.aspx

Reimbursement – Medicaid

- 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
- 48 provide some coverage for mental or behavioral health services delivered via live video
- 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

Questions?

Kim McWhorter
MedZed
www.mymedzed.com
kmcwhorter@mymedzed.com

Sidney S. Welch
Polsinelli PC
www.polsinelli.com
swelch@polsinelli.com
404.253.6047