Telemedicine: Regulatory Compliance Concerns in a Rapidly Changing Environment

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22nd annual Compliance Institute

Telemedicine

- Overview
- 5 Key Compliance Areas:
  1. Public and Private Payor Reimbursement
  2. Licensure/Credentialing
  3. Privacy and security legal requirements
  4. Fraud and abuse
- Suggested Audit Approaches
Broadly Speaking….

**TELEHEALTH**

Telehealth is defined as the use of telecommunications and information technologies to share information, and provide clinical care, education, public health, and administrative services at a distance.¹

**Telemedicine**

*The practice of medicine using electronic communication, information technology or other means between licensee in one location, and a patient in another location with or without an intervening healthcare provider.*²

Examples of services: PC and specialist referral services, remote patient monitoring.³

Examples of delivery mechanisms: networks between healthcare centers, point-to-point connections between healthcare centers and independent providers, remote monitoring systems, telemedicine-based e-health patient service sites.³

**mHealth**

*mHealth is the use of mobile and wireless devices to improve health outcomes, healthcare services and health research.*⁵

¹ HRSA, Telehealth Programs, available at https://www.hrsa.gov/ruralhealth/telehealth/
² Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine, Proposed Uniform Definition of Telemedicine, FSMB (April 2014)
³ American Telemedicine Association, “What is Telemedicine?”

How is Telemedicine Being Used

- Fast and simple diagnostic
- Distant monitoring
- Mobile medicine
Says Who?

“The practice of medicine occurs **where the patient is located at the time telemedicine services are used**, and insurers may issue reimbursements based on where the practitioner is located. Therefore, a **practitioner must be licensed by, or under the jurisdiction of, the regulatory board of the state where the patient is located and the state where the practitioner is located**. Practitioners who treat or prescribe through online service sites must possess appropriate licensure in all jurisdictions where patients receive care. To ensure appropriate insurance coverage, practitioners must make certain that they are compliant with federal and state laws and policies regarding reimbursements.”

— Virginia Board of Medicine Telemedicine Guidance 85-12 (July 22, 2017)
Am I doing it?

Virginia

"Telemedicine service" as it pertains to the delivery of health care services, means the use of electronic technology or media, including interactive audio or video, in the process of diagnosing or treating a patient or consulting with other health care providers, requiring a patient's diagnosis or medical attention. "Telemedicine service" does not include an audio-only telephone, electronic mail message, facsimile transmission, or other communication. Va. Code § 38.2-3418.16

Washington D.C.

"Telemedicine" means the practice of medicine by a licensed practitioner to provide patient care treatment or services, between a licensee in one location and a patient in another location with or without an intervening healthcare provider, through the use of health information and technology communications, subject to the existing standards of care and conduct. Generally, telemedicine is not an audio-only telephone conversation, electronic mail or instant messaging conversation or via fax. Washington D.C. Dept. of Health Regulations and Licensing Administration Board of Medicine, Policy No. 15-01

Maryland

"Telemedicine" means the practice of medicine from a distance in which intervention and treatment decisions and recommendations are based on clinical data, documents, and information transmitted through telecommunications systems. COMAR 10.32.05.02 Definitions.

Can We?

Virginia

Provisions of VA regulations on the practice of medicine shall not prevent or prohibit:
Any legally qualified out-of-state or foreign practitioner from meeting in consultation with legally licensed practitioners in this Commonwealth;

The rendering of medical advice or information through telecommunications from a physician licensed to practice medicine in Virginia or an adjoining state, or from a licensed nurse practitioner, to emergency medical personnel acting in an emergency situation.

Va. Code Ann. § 54.1-2901

Washington D.C.

Provisions prohibiting the practice of a health occupation without a D.C. license do not apply to:
To a health professional who is authorized to practice a health occupation in any state adjoining the District who treats patients in the District if: (A) The health professional does not have an office or other regularly appointed place in the District to meet patients; (B) The health professional registers with the appropriate board and pays the registration fee prescribed by the board prior to practicing in the District; and (C) The state in which the individual is licensed allows individuals licensed by the District in that particular health profession to practice in that state under the conditions set forth in this section. DC Statute § 3-1205.02

Maryland

Subject to the rules, regulations, and orders of the Board, the following individuals may practice medicine without a license: a physician licensed by and residing in another jurisdiction, while engaging in consultation with a physician licensed in this State; a physician who resides in and is authorized to practice medicine by any state adjoining this State and whose practice extends into this State, if the physician does not have an office or other regularly appointed place in this State to meet patients, and the same privileges are extended to licensed physicians of this State by the adjoining state.

Annotated Code of Maryland, HEALTH OCCUPATIONS, §14-302
Virginia
“The Virginia General Assembly has not established statutory parameters regarding the provision and delivery of telemedicine services. Therefore, practitioners must apply existing laws and regulations to the provision of telemedicine services.” Telemedicine Guidance Document 85-12

“The practitioner is responsible for making this determination [whether services are appropriate through telemedicine or an in-person evaluation], and in doing so must adhere to applicable laws and standards of care.” Telemedicine Guidance Document 85-12

Washington D.C.
“Physician-patient relationship” means a relationship between a physician and a patient in which there is an exchange of an individual’s protected health information for the purpose of providing patient care treatment or services. Telemedicine Policy No. 15-01.

A physician shall perform a patient evaluation adequate to establish diagnoses and identify underlying conditions or contraindications to recommended treatment options before providing treatment or prescribing medication. Telemedicine Policy No. 15-01 Sec. 1.6.

If a physician-patient relationship does not include prior in-person, face-to-face interaction with a patient, the physician shall incorporate real-time auditory communications or real-time visual and auditory communications to allow a free exchange of protected health information between the patient and the physician performing the patient evaluation. Telemedicine Policy No. 15-01 Sec. 1.8.

Maryland
A. A physician shall perform a patient evaluation adequate to establish diagnoses and identify underlying conditions or contraindications to recommended treatment options before providing treatment or prescribing medication.

B. A Maryland-licensed physician may rely on a patient evaluation performed by another Maryland-licensed physician if one physician is providing coverage for the other physician.

C. If a physician-patient relationship does not include prior in-person, face-to-face interaction with a patient, the physician shall incorporate real-time auditory communications or real-time visual and auditory communications to allow a free exchange of information between the patient and the physician performing the patient evaluation. Md. Code Regs. 10.32.05.05

State Medical Board – Standard of Care

Evaluation that meets applicable “Standard of Care”
- Identify patient
- Gather information
- (Face-to-face or real time audio video conferencing)

Informed Consent
- Patients should receive information necessary to make a meaningful decision about their medical care and treatment

Diagnosis
- Physician’s discretion to collect necessary information

Treatment
- Prescription of medicine

Follow-up care
- Ensure availability of f/u care by a physician located in patient’s state
- Establish an emergency situation referral plan

Documentation
- Confidentiality/EHR Requirements
- Maintain patients’ medical records and make available to both patients and patient’s health care providers

Continuous care
- Mostly prohibited through telemedicine [generally, for out of state physicians]
Or Else?

- Reprimand or censure
- Impose a monetary penalty, which goes to the state literary fund.
- Require remedial or corrective action
- Require a licensee to meet probationary requirement
- Limit a licensee’s practice privileges and/or
- Suspend or revoke a license

Civil Action:
In addition to any possible board action, the Department will work with all appropriate law enforcement agencies and prosecutors if information indicates that a criminal law may have been violated. Actions by boards and by the criminal justice system are taken separately.

Who Will Pay? (Insurance Coverage)

**Virginia**
- “Telemedicine services,” as it pertains to the delivery of health care services, means the use of interactive audio, video, or other electronic media used for the purpose of diagnosis, consultation, or treatment. “Telemedicine services” do not include an audio-only telephone, electronic mail message, or facsimile transmission.

*Va. Code Ann. § 38.2-3418.16 adopted by VA Board of Medicine*

**Washington D.C.**
- “Telehealth” means the delivery of healthcare services through the use of interactive audio, video, or other electronic media used for the purpose of diagnosis, consultation, or treatment; provided, that services delivered through audio-only telephones, electronic mail messages, or facsimile transmissions are not included.

* D.C. Code § 31-3861

**Maryland**
- “Telemedicine” means, as it relates to the delivery of health care services, the use of interactive audio, video, or other telecommunications or electronic technology:
  A. By a health care provider to deliver a health care service that is within the scope of practice of the health care provider at a site other than the site at which the patient is located; and
  B. That enables the patient to see and interact with the health care provider at the time the health care service is provided to the patient.
- “Telemedicine” does not include:
  A. An audio-only telephone conversation between a health care provider and a patient;
  B. An electronic mail message between a health care provider and a patient; or
  C. A facsimile transmission between a health care provider and a patient.

* MD Code Ins. 15-139 (Maryland Code (2017 Edition))
To Summarize... Telemedicine

- Where is the patient?
- Am I doing it?
- Diagnosing and treating patient electronically?
- Or else?
  - Loss of license
  - Civil and criminal liability
  - Does it meet regulatory definition of telemedicine/telehealth?

Says who?

Am I licensed there? Or does an exception apply?

What is the standard of care?

Can I?

Who will pay?

PUBLIC AND PRIVATE PAYOR REIMBURSEMENT
Reimbursement 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

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.
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.
### Telehealth Coverage & Reimbursement

#### CY 2018 Medicare Telehealth Services (cont.)

<table>
<thead>
<tr>
<th>Service Description</th>
<th>HCPCS Code</th>
<th>CPT Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual depression screening, 15 minutes</td>
<td>HCPCS code 99440</td>
<td>CPT code 99354</td>
</tr>
<tr>
<td>High priority behavioral counseling (e.g., tobacco cessation, weight management, diabetes management)</td>
<td>HCPCS code 99450</td>
<td>CPT code 99355</td>
</tr>
<tr>
<td>Annual, face-to-face, multimodal behavioral therapy for diabetes mellitus, including with other conditions</td>
<td>HCPCS code 99460</td>
<td>CPT code 99356</td>
</tr>
<tr>
<td>Mental health behavioral counseling for diabetes, 15 minutes</td>
<td>HCPCS code 99470</td>
<td>CPT code 99357</td>
</tr>
<tr>
<td>Transitional care management services with moderate complexity</td>
<td>CPT code 99405</td>
<td></td>
</tr>
<tr>
<td>Transitional care management services with high complexity</td>
<td>CPT code 99410</td>
<td></td>
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<tr>
<td>Advanced Care Planning, 30 minutes effective for services furnished on or after January 1, 2017</td>
<td>CPT code 99457</td>
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<tr>
<td>Advance Care Planning, additional 15 minutes effective for services furnished on or after January 1, 2017</td>
<td>CPT code 99465</td>
<td></td>
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<tr>
<td>Psychosocial</td>
<td>CPT code 90804</td>
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</tr>
<tr>
<td>Family therapy (without the patient present)</td>
<td>CPT code 90845</td>
<td></td>
</tr>
<tr>
<td>Family therapy (with the patient present)</td>
<td>CPT code 90846</td>
<td></td>
</tr>
<tr>
<td>Prophylactic services in the office or other certified setting requiring direct patient contact beyond the usual visit</td>
<td>CPT code 90864</td>
<td></td>
</tr>
<tr>
<td>Prophylactic services in the office or other certified setting requiring direct patient contact beyond the usual visit, each additional 15 minutes</td>
<td>CPT code 90865</td>
<td></td>
</tr>
<tr>
<td>Prophylactic services in the hospital setting requiring direct patient contact beyond the usual visit, each additional 15 minutes</td>
<td>CPT code 90866</td>
<td></td>
</tr>
</tbody>
</table>

**Note:**
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### Telehealth Coverage & Reimbursement

#### CONNECT for Health Act

**Purpose:** To improve health and access to care.

- **Health Benefits:**
  - **Health Insurance:** Coverage for telehealth services.
  - **Medicare:** Allows Medicare to cover telehealth services.
  - **Insurers:** Requires insurers to cover telehealth services.
  - **Telehealth Services:** Includes services that are typically provided in person.

- **Connecticut Health Insurance Exchange:**
  - **保费：**
    - **保费：**
  - **保费：**

- **Connecticut's State Innovation Experiment (SIET):**
  - **保费：**
  - **保费：**

- **Health Information Technology for Economic and Clinical Health (HITECH) Act:**
  - **保费：**
  - **保费：**

- **Health Care Quality and Transparency Act:**
  - **保费：**
  - **保费：**

- **Medicaid Telerehabilitation:**
  - **保费：**
  - **保费：**

- **Medicare Advantage:**
  - **保费：**
  - **保费：**

- **Medicare Durable Medical Equipment:**
  - **保费：**
  - **保费：**

**Additional Resources:**
- [ CONNECT for Health Act](#)
- [Connecticut Health Insurance Exchange](#)
- [SIET](#)
- [HITECH Act](#)
- [Health Care Quality and Transparency Act](#)
- [Medicaid Telerehabilitation](#)
- [Medicare Advantage](#)
- [Medicare Durable Medical Equipment](#)

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**Note:**
- The information provided is for educational purposes and should not be considered medical advice.
- More information can be found at [Healthcare.gov](#) and [Medicare.gov](#).

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**Source:**
- [Healthcare.gov](#)
- [Medicare.gov](#)
Promising Legal Developments: The CONNECT Act

- The Creating Opportunities Now for Necessary and Effective Technologies (CONNECT) for Health Act of 2017
- Bipartisan Legislation
- Purpose: “To promote cost savings and quality care through the use of telehealth and remote patient monitoring (RPM) services.”
- Provisions:
  - Waives 42 U.S.C. 1834(m) reimbursement restrictions for eligible applicants and qualifying APM participants when quality and cost-effectiveness measures are satisfied (encourages transition to goals of MACRA and MIPS)
  - Permits the use of RPM for patients with certain chronic conditions
  - Expands the scope of originating sites to include telestroke evaluation and management sites, Native American health service facilities, and dialysis facilities for home dialysis patients in certain cases
  - Permits further telehealth and RPM in community health centers and rural health clinics
  - Allows telehealth and RPM to be basic benefits in Medicare Advantage without most of the 42 U.S.C. 1834(m) restrictions
  - Clarifies that the provision of telehealth or RPM technologies made under Medicare by a healthcare provider for the purpose of furnishing these services shall not be considered “remuneration”
- Projected Savings = $1.8 Billion over the next 10 years (Avalere Analysis)
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.

Medicaid Coverage

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

State Telehealth Laws and Medicaid Program Policies

**DEFINITION**
- 49 states and the District of Columbia have a definition for telehealth, telemedicine, or both

**LOCATION**
- a few states have required a certain amount of distance between the provider and patient
  - In North Carolina, originating and distant site must be of a sufficient distance apart
  - In South Dakota, an originating site and a distant site cannot be in the same community

**CONSENT**
- 30 states include some sort of informed consent

**PRIVATE PAYER LAWS**
- 36 states and the District of Columbia have active laws

**MEDICAID REIMBURSEMENT**
- 48 states & DC reimburse for live video through Medicaid
- 21 states reimburse for remote patient monitoring
- 1 state only reimburses through their Department of Aging Services

**ONLINE PRESCRIBING**
- Internet-based prescriptions are not allowed, states may require a physical exam prior to a prescription

**CROSS STATE LICENSURE**
- 9 states issue special licenses or certificates for telehealth

**LICENSING AND CREDENTIALING**

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By Polsinelli

In 2017 Polsinelli published a white paper on connected health policy, which can be found at [Polsinelli's website](https://www.polsinelli.com/).
Licensure/Credentialing 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

- Federal (Medicare), State, or Accreditation Agency (e.g., The Joint Commission) Credentialing Requirements

Licensure-Prescribing 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
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. 8 states – LA, MN, NM, NV, OH, OR, TN, TX have special telehealth licenses.

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.
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]."
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.
• 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
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.
Privacy & Security Checklist

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

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.
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.

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.

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.

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
Fraud & Abuse 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
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

“knowingly and willfully”

Penalties

- **Criminal**
  - Fine (up to $25,000)
  - Jail (up to 5 years)

- **Civil**
  - Fine (up to $50,000)
  - 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
### 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/)
Stark Penalties

- Civil
  - Fine (up to $15,000 per 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.
  - Failing to report and return an identified overpayment IAW 60 day refund rule

Stark 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
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://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

False Claims Act (FCA)

- Federal Government’s Primary Fraud Enforcement Tool
- What Does FCA Do? It imposes liability for:
  - Knowingly presenting or causing to be presented, a false or fraudulent claim for payment or approval;
  - Knowingly making, using, or causing to me made or used, a false record or statement material to be a false or fraudulent claim;
  - Conspiring to commit a substantive violation; OR
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government.
- Penalties: Treble Damages, Per-Claim Penalties, Costs of the Civil Action, Relator’s Reasonable Expenses and Attorney’s Fees
- 31 U.S.C. 3729(a)(1)
FCA and Telehealth

- **July 2016**: FCA Settlement between Connecticut Psychiatrist/Mental Health Practice and the U.S. Attorneys Office involving Claims for Telehealth Services

- **What Happened?** The psychiatrist and his practice allegedly submitted improper claims to Medicare for psychiatric services that were provided over the phone to Medicare beneficiaries, instead of by meeting with the beneficiaries in the office and treating them in person.

- **Problem?** Medicare permits certain types of “telehealth” services where (a) the patient is in a rural health professional shortage area and (b) where the provider uses an interactive audio and video communications system that permits real-time communication between the provider and the patient. Does not permit reimbursement for services provided via telephone.

- **Settlement Amount?** $36,704 (small sum, but USAO involvement signals increased focus on practitioners employing telehealth services)
Audit Approach

- OIG’s October 2017 work plan addition states:
  - “We will review Medicare (Part B) claims paid for telehealth services provided at distant sites that do not have corresponding claims from originating sites to determine whether those services met Medicare requirements.”
  - The OIG has also announced it will audit Medicaid payments for telemedicine and telehealth in 2018 with a report due in 2019.

- To audit:
  1. Where is the originating site?
  2. What is the originating site?
  3. Who is providing the services?
  4. How is the services delivered?
  5. What CPT/HCPC code is being billed?

Questions?