


Telemedicine
How to Set up a Compliant Telemedicine Program

Panel Members

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Discussion Topics

- * **Understanding the Technology**
- * **Understanding the Legal & Regulatory Risks**
 - * Protecting your health information
 - * Legal Considerations
 - * Credentialing Considerations
- * **Understanding information security and other risks.**
 - * Encryption
 - * Data Storage




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Telemedicine Drivers

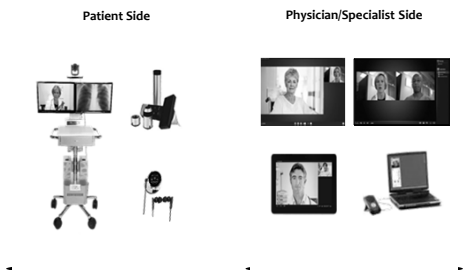
- * Shift from treating the ill to preventing illness with associated cost reduction
- * Prevention and wellness: reducing re-hospitalizations, population management
- * Patient Centered Care: web portals, geography independent demand
- * Practitioner shortage: increased distributed demand for all levels of healthcare team
- * Rising Costs
- * Aging population
- * Chronic Disease
- * Home health
- * Patient Centered Care/Prevention
- * Care pushed to community health centers



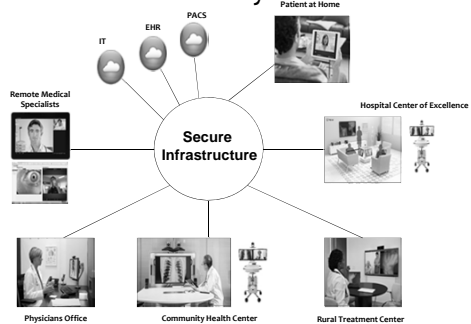
Collaborative Healthcare Applications

Healthcare Administration	Medical Education	Telemedicine Applications	Patient Centered Care
<ul style="list-style-type: none"> • Board meetings • Recruitment and interviewing • Project management • Supplier & vendor relations 	<ul style="list-style-type: none"> • Practitioner Education • Continuing Med. Education • Internal training • Professional Development • Prevention and Wellness 	<ul style="list-style-type: none"> • Primary Care • Mental Health • Dermatology • Cardiology • Infectious Disease • Pediatrics • Clinical care to the home 	<ul style="list-style-type: none"> • Case management • Discharge planning • Collaborative care teams • Multi-disciplinary teams • Peer to peer • Health Coach • Tumor Boards

Telemedicine Solution Components



Collaborative Healthcare Connectivity Model



Compliance Indicators

Encryption

HIPAA guidelines require that any software transmitting protected personal health information meet a 128-bit level of encryption.

BAA Example

In order to comply with the HIPAA Omnibus Rule, Skype would need to enter into a business associate agreement (BAA) with any health provider concerned about HIPAA compliant telehealth. Since consumer Skype wasn't designed for healthcare purposes, BAAs are not available.

Consumer App Cautions

Consumer grade technologies are typically determined as high risk beyond the security requirements. Apps like Facetime, Consumer Skype and Google Hangouts should be carefully evaluated for compliance. They often meet minimum Encryption requirements, but fall short in providing required call statistics for patient encounters.



HIPAA and Telehealth



Compliance with the Health Insurance Portability and Accountability Act (HIPAA) is more complex than simply using products that claim to be "HIPAA-compliant."

HIPAA compliance entails an organized set of secure, monitored, and documented practices within and between covered entities.

Though products cannot ensure compliance, some products may contain elements or features that allow them to be operated in a HIPAA-compliant way.

Source: National Telehealth Policy Resource Center www.telehealthpolicy.us



Presentation to HCCA's Nashville Annual Regional Conference

Telemedicine Legal and Regulatory Issues

November 17, 2017

Presented by: Judd Harwood

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CROSS-STATE LICENSURE

- * Most states require physicians to be licensed to practice in the originating site's state, and some states require providers using telehealth technology across state lines to have a valid state license in the state where the patient is located.
- * Some state medical boards will issue special licenses or certificates related in some way to telehealth.
- * Other states have laws that don't specifically address telehealth/telemedicine licensing but make allowances for contiguous states or for certain situations where a temporary license might be issued, provided the specific state's licensing conditions are met.
- * State also regulate non-physicians involved in telemedicine activities.

INFORMED CONSENT

- * Some states require some form of informed consent documented in the patient's records before a provider can provide any telemedicine service.
- * The Informed consent is used to explain what telemedicine is, and lay out the expected benefits and possible risks associated with it to a patient.
- * It can take the form of a written form which needs to be signed by the patient and/or oral acknowledgement that is noted in the patient's record.
- * The AMA has issued ethical guidelines for physicians who provide telemedicine (Opinion E-5.025).

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MALPRACTICE ISSUES

- * The number of malpractice and other types of claims involving telemedicine remains small, but it is expected to rise as telemedicine encounters becomes more commonplace.
- * When using telemedicine, providers must be confident in their ability to diagnose and manage patients.
- * They must also be aware of any limitations related to this type of virtual encounter using information communication technology.
- * The same issues regarding breaches in the standards of care and potential negligence can occur when using telemedicine as during in-person encounters with patients or in support of their primary care providers.

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MALPRACTICE ISSUES

- * Malpractice insurance policies should be examined to determine if telemedicine encounters are directly addressed or if additional coverage is necessary.
- * Some malpractice policies only cover telemedicine services when the services are performed within the State in which the provider practices, but not outside the State leaving providers open to uninsured claims against them if they use telemedicine to connect with patients in other states.
- * This is particularly true for offshore telemedicine providers, who may be unable to purchase coverage for claims in the United States.

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CORPORATE PRACTICE OF MEDICINE AND FEE SPLITTING ISSUES

Corporate Practice of Medicine:

- * In a majority of the states, only licensed healthcare providers are allowed to own or control a company that is "practicing medicine."
- * While variations exist among states, the corporate practice doctrine generally forbids a person or entity other than a licensed physician, professional corporation or a professional limited liability company, from owning an interest in a medical practice or employing physicians for the purpose of practicing medicine.

Fee Splitting:

- * In addition, most states prohibit physicians from "splitting" their fees with non-physicians and from participating in illegal patient referral kickback schemes.
- * The distinction between illegal fee splitting and legitimate payments for non-medical services is not well defined.

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PRIVACY AND SECURITY

- * Issues regarding privacy and confidentiality in the medical realm are not necessarily different in telemedicine.
- * Providers are required to comply with the same HIPAA requirements whether they are delivering services through telemedicine/telehealth or in-person.
- * As with conventional medicine, a telemedicine clinician has the same duty to safeguard a patient's medical records and keep their treatments confidential.
- * Storage of electronic files, images, audio/video tapes etc., needs to be done with the same precaution and care ascribed to paper documents.

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PRIVACY AND SECURITY

- * While HIPAA does not prohibit offshoring, offshoring concerns should be taken into account in conducting the risk analysis and risk management required by the Security Rule. Note that state laws may prohibit offshoring arrangements.
- * The OCR has noted that "offshoring may increase the risk and vulnerability to information or present special considerations with respect to the enforceability of privacy and security protections over the data."
- * Prior to entering into an offshore arrangement, a healthcare provider should, at a minimum independently assess and/or audit the vendor's administrative, physical and technical safeguards. Other issues that need to be addressed: (i) venue and governing law, (ii) ability to subcontract services, (iii) development incident response plans, (iv) background searches, (v) continuing audit rights and (vi) indemnification.

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PRESCRIPTIONS – FEDERAL REGULATION

Federal Regulation:

- * In October 2008, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was signed into law, amending the Controlled Substances Act (CSA) by defining legally permissible activities for physicians prescribing controlled substances over the Internet.
- * The law expressly requires an in-person physical examination before a physician may prescribe a controlled substance, unless an express exception created under the law applies.
- * The Haight Act also includes seven narrow exceptions that allow telemedicine providers to prescribe medications without having to meet with the patient in-person.
- * The narrowness of the exceptions has generally left telemedicine providers without the ability to prescribe controlled substances for their patients.

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PRESCRIPTIONS – STATE REGULATION

State Regulation:

- * State laws generally require that a physician first establish a valid physician-patient relationship before the physician may write a prescription for a patient.
- * In most states a physical examination or evaluation of the patient must be performed prior to issuance of a prescription by the prescribing physician.
- * But, the definition of a valid “physical examination” varies from state to state and what constitutes a “physical examination” is critical.
- * Some states require at least one in-person consultation to establish a patient-provider relationship.
- * Twenty states explicitly allow physical examinations or evaluations to be performed by electronic means or via telehealth technologies and states have generally moved in the direction of loosening restrictions.

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FRAUD AND ABUSE LAWS

Federal Regulation:

- * Telemedicine arrangements can implicate the Anti-Kickback Statute by inducing referrals for which federal health care program reimbursement is available.
- * The OIG has published three advisory opinions addressing telemedicine-related issues.
- * Telemedicine arrangements should also be analyzed for possible self-referral risks and self-referral exceptions.
- * Telemedicine activity that involves violation of the Anti-Kickback Statute or self-referral laws could be subject to additional sanctions under the False Claims Act and the Civil Monetary Penalties.

State Regulation:

- * Telemedicine arrangements will also be subject to any self-referral and anti-kickback laws of the states into which the arrangement may reach.

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TELEMEDICINE CREDENTIALING IN THE HOSPITAL SETTING

Sources of Authority

- CMS Conditions of Participation (“CoPs”) & Interpretive Guidelines
 - 42 CFR § 482.12; 42 CFR § 482.22
- Joint Commission (“TJC”) Standards
 - LD 04.03.09; MS 13.01.01
- Hospital Medical Staff Bylaws
- Credentialing Agreements

CMS Requirements

- Hospital medical staffs and boards MAY rely on distant site entity information AND privileging decisions when credentialing telemedicine providers as long as –
 - ❖ Written agreement between Hospital and:
 - distant site hospital that participates in the Medicare Program; OR
 - Distant-site telemedicine entity that provides services in a manner consistent with the CoPs.

CMS Requirements (cont.)

- ❑ **Written agreement must contain the following representations and requirements:**
 - ❖ The credentialing and privileging processes at the distant site meet all applicable CoPs;
 - ❖ Telemedicine providers hold valid license in the state where the Hospital is located (and the state where the physician is located, if required by applicable state law);
 - ❖ Telemedicine providers are privileged at the distant site and distant site provides privilege list to Hospital;
 - ❖ Hospital agrees to collect evidence of telemedicine provider performance and sends this information to the distant site.

TJC Requirements

- ❑ **Requires originating site to have an agreement with the distant site containing the following elements:**
 - ❖ Distant site is a contractor of services to Hospital.
 - ❖ Distant site provides services in compliance with CoPs.
 - ❖ The credentialing and privileging processes at distant site comply with CoPs.

TJC Requirements (cont.)

- ❑ **Three distinct options for credentialing telemedicine providers:**
 - ❖ **Option 1** – Hospital fully credentials telemedicine providers (standard bylaws/TJC process).
 - ❖ **Option 2** – Hospital medical staff and board credential telemedicine providers using credentialing *information* from the distant site if:
 - Distant site is TJC accredited; **AND**
 - Telemedicine providers hold valid license in the state where the Hospital is located.

TJC Requirements (cont.)

- ❖ **Option 3** – Hospital medical staff and board credential telemedicine providers using credentialing information AND **decisions** from the distant site if:
 - Distant site is TJC accredited and complies with TJC Medical Staff (MS) Chapter requirements.
 - Telemedicine provider is privileged at distant site for services he/she will provide at Hospital, and distant site provides privilege list to Hospital.

TJC Requirements (cont.)

- ❖ **Option 3 (cont.)** –
 - Telemedicine providers hold valid license in the state where the Hospital is located.
 - Hospital agrees to collect evidence of telemedicine provider performance and sends this information to the distant site.
 - Includes adverse outcomes related to TJC sentinel events.

Medical Staff Bylaws

- The Medical Staff Bylaws must clearly describe the credentialing processes and procedures for the privileging of telemedicine providers.**
 - Bylaws language considerations and options?
- We must ensure that we do not deviate from the procedures outlined in the Medical Staff Bylaws, regardless of any contrary contract language.**
 - Why?/Risks?

Template Credentialing Contracts

- ❑ Hospitals should develop template telemedicine credentialing contracts or template agreement language.
 - ❖ Such an agreement/language is required if the facility would like to utilize a form of distant site credentialing .
 - ❖ Advantages of using your own contract/language as opposed to vendor language.
- ❑ These agreements should address all necessary TJC, CMS, and bylaws requirements with respect to distant site credentialing.

How to set up a Compliant Telemedicine Program

- ❑ Drivers include increased treatment options and greater convenience for patients and providers.
- ❑ Appropriate use can lead to decreased cost and increased patient/provider satisfaction
- ❑ Establish a secure and sustainable telemedicine infrastructure

How to set up a Compliant Telemedicine Program

- ❑ Address Legal and regulatory concerns
 - ❖ Cross-state licensure
 - ❖ Informed Consent
 - ❖ Malpractice
 - ❖ Credentialing/Privileging in the Hospital Setting
 - ❖ Corporate Practice of Medicine
 - ❖ Privacy and Security
 - ❖ Prescription Regulations
 - ❖ Potential for Fraud and Abuse

Questions?

Thank you!
