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Drafting Agreements for TeleHealth And Mobile Health Platforms, Healthcare Organizations and Physician Groups EndUsers
Navigating Regulatory Compliance and Corporate Practice of Medicine Issues, Negotiating Key Provisions

WEDNESDAY, MAY 18, 2016
1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today’s faculty features:

Noel Christian Pace, JD, MHA, FACHE, The Law Offices of John MacDaniel, Miami
Pete Salsich, III, General Counsel, MedAware Solutions, St. Louis
Tips for Optimal Quality

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Drafting Agreements for TeleHealth And Mobile Health Platforms, Healthcare Organizations and Physician Groups EndUsers
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May 18, 2016
The Health Facility CEO’s Perspective on TeleHealth and Mobile Health Platform Agreements: Telemedicine Trends and Emerging Platforms

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Internet use exploded once content became accessible and useful.

Today, health care information technology (HIT) is at the “1999” of the Internet age

Source: U.S. Census Bureau, Population Division, Education & Social Stratification Branch, “Reported Internet Usage for Households, by Selected Householder Characteristics:,2007”; Texas eHealth Alliance: Nora Belcher
Trends that are driving or hindering TeleHealth and Mobile Health Platform adaptation.

• **Industry**¹
  - Increased patient demand as a result of the Affordable Care Act
  - Primary care physician shortage
  - A less mobile and aging population

• **Regulation**²
  - Barriers to entry include State Licensure requirements

• **Reimbursement**³, ⁴
  - The Doc Fix
  - American Telemedicine Association (ATA) Reports

• **Technological Disruption**
  - Must be accounted for by your organization’s leadership

Technological disruption must be accounted for in Telehealth and Mobile Health Platform agreements.

- Doctor’s Care in South Carolina and Tennessee is reducing wait times in Urgent Care.¹
- Just in the past few years, CVS has gone from dispensing medication to prescribing it (and dispensing).

Technological disruption must be accounted for in Telehealth and Mobile Health Platform agreements.

• Dr. Robot is on call...

• And, CVS is now upping the ante in conjunction with the Cleveland Clinic.¹

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the new Merit Based Incentive Payment System (MIPS)

• **Repeals the sustainable growth rate (SGR) for Physician Fee Schedules**\(^1\)
  – Basically transitions from fee-for-service to fee-for-value

• **Establishes MIPS**
  – Consolidates components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals (EPs).

• **Impact on Reimbursement for TeleHealth and Mobile Health Platforms?**\(^2, 3, 4\)
  – Medicare’s perspective vs. DOD’s and VA’s way ahead.
  – Congress may be taking action—CMS too.

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1. [http://geekdoctor.blogspot.com/2016/05/a-deep-dive-on-macra-nprm.html?utm_medium=nl&utm_source=internal&mkttok=eyJpIjoiWWpBMU9URTBPVGYzTVRSaSIsInQiOiJ5RmxWXC9XVWZaQTc0azQ0M3ZaemlERUdhOHL1eH ZiQ3ZuQ0NLaHFIdDlvWUtNcWZmZ2ExcWN5cmZyVE ExxonRGxvQ292ZFBIm1vbmd5bzg0aUFSVJGNUODQ2ejBtMW1ucXd5Z2dKdWpkNhV0E9In0%3D](http://geekdoctor.blogspot.com/2016/05/a-deep-dive-on-macra-nprm.html?utm_medium=nl&utm_source=internal&mkttok=eyJpIjoiWWpBMU9URTBPVGYzTVRSaSIsInQiOiJ5RmxWXC9XVWZaQTc0azQ0M3ZaemlERUdhOHL1eH ZiQ3ZuQ0NLaHFIdDlvWUtNcWZmZ2ExcWN5cmZyVE ExxonRGxvQ292ZFBIm1vbmd5bzg0aUFSVJGNUODQ2ejBtMW1ucXd5Z2dKdWpkNhV0E9In0%3D)
Last Point: In whatever you agree to in your “agreements,” you must get the physicians on board first.

• Physicians are the key revenue “engines” in your facilities.
• TeleHealth and Mobile Health Platforms (depending on the facts: your state, reimbursement policies, regulatory requirements) may be used to:
  • 1) Get more engines running when they are idle (based on demand patterns) or;
  • 2) Act as a turbo boost (21st Century Stethoscope) to increase their productivity and effectiveness.
• However, their use (and corresponding Return on Investment) will never be effectively realized if you don’t get the doctors on board first.
Regulatory Compliance in TeleHealth and Mobile Health Platforms

Anjali B. Dooley, JD, MBA
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Who is regulating telemedicine & mHealth?

**Consumer Protection/Provider Regulations**

**Who Enforces?**

- HIPAA (Health Insurance Portability & Accountability Act) & HITECH (The Health Information Technology for Economic and Clinical Health Act) --- (OCR/DOJ)

  - Separate and unrelated laws, but they do reinforce each other in certain ways. For example, HITECH stipulates that technologies and technology standards created under HITECH do not compromise HIPAA privacy and security laws.

  - Defines policies, procedures and guidelines for maintaining the privacy and security of protected health information (PHI) as well as outlining numerous offenses relating to health care and sets civil and criminal penalties for violations of the security and privacy regulations.
Who is regulating telemedicine & mHealth? (con’t)

**Consumer Protection/Provider Regulations**

**Who Enforces?**

- Federal Trade Commission (FTC)—extension of HIPAA notification:
  
  - FTC’s Health Breach Notification Rule: the nation’s consumer protection agency, has issued the Rule to require certain businesses not covered by HIPAA to notify their customers and others if there’s a breach of unsecured, individually identifiable electronic health information.
  
  - The Rule applies if you are: (1) a vendor of personal health records (PHRs); (2) a PHR-related entity; or (3) a third-party service provider for a vendor of PHRs or a PHR-related entity.
  
  - The Who, What, When, and How to notify under this rule?

  - LabMD, Inc. v. FTC
Who is regulating telemedicine & mHealth? (con’t)

**Consumer Protection/Provider Regulations**
**Who Enforces?**

- Federal Communications Commission (FCC)
  - Regulates devices that utilize electromagnetic spectrum, or broadcast devices.
  - Regulates the device as a communications device, not as a medical device.
  - Overlapping jurisdictions, the FCC and FDA entered into a MOU where they would collaborate with each other.
  - TCPA (Telephonic Consumer Protection Act) governed by FCC, Recent Declaratory Ruling, CVS Pharmacy & Robo Calls (ATDS)
Who is regulating telemedicine & mHealth? (con’t)

Consumer Protection/Provider Regulations
Who Enforces?

✔ Food & Drug Administration (FDA)

- Plays a critical regulatory role in ensuring the safety and effectiveness of telemedicine medical devices and software with the Center for Devices and Radiological Health (CDRH) acting as lead agency.

- If the equipment or software is intended for use in the diagnosis or treatment of a disease or other condition, FDA considers the equipment or software to be a medical device.

- FDA also regulates the software used in telehealth systems. (Ex) Medical Imaging Software.
Who is regulating telemedicine & mHealth? (con’t)

Consumer Protection/Provider Regulations

- State Privacy Laws (State Attorney Generals)
- State Medical Boards/Dental Boards/Pharmacy Boards—Missouri Board of Healing Arts
- Medical Staff Bylaws – What do the hospital bylaws say?
Telemedicine Compliance Best Practices

KNOW YOUR PLATFORM: RECENTLY THE FTC CAME UP WITH A INTERACTIVE TOOL FOR MOBILE APPLICATION DEVELOPERS that collects, creates, or shares consumer information. Most applications that are being created whether for texting, video conferencing or communications are SaaS (Software As A Service) platforms.

THE INTERACTIVE TOOL found on the Federal Trade Commission’s website, the developers can find out when FDA, Federal Trade Commission (FTC) or Office of Civil Rights (OCR) laws apply!

Telemedicine Compliance Best Practices

1. Know the Laws

2. Conduct A Risk Analysis

3. Draft Appropriate Policies & Procedures in case of Data Breaches

4. Execute a Business Associate Agreement (PHI)

5. Be Transparent with C-Suite, Board of Directors, and Governmental Entities

6. Be a team player: Your CTO, CISO, GC and CEO are your best friends as a Chief Compliance Officer.

---From the perspective of a Chief Compliance Officer
INNOVATION vs. COMPLIANCE: Can Compliance Drive Innovation?
Protecting Your IP and Building Relationships: TeleHealth and Mobile Health Platform Agreements from the Provider’s Point of View

Pete Salsich III, JD – General Counsel
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Emergence of TeleHealth/mHealth Platforms Creates Opportunities and Risk for Tech Companies

**Opportunities:** “A recent study from business information provider IHS predicts the US telehealth market will grow from $240 million in revenue in 2013 to $1.9 billion in 2018 — an annual growth rate of more than 50%.” – Ernst & Young


**Risk:** “More than half of digital health start-ups funded between 2008 and 2013 are not likely to survive longer than 20 months.” – Accenture

TeleHealth Companies are Technology Companies
= They are defined by their Intellectual Property

• All TeleHealth / mHealth Products are built on IP
• Counsel needs to ask certain questions before drafting:

  • **WHAT IS IT?** -- What types of IP are involved?
    • Patents/Copyrights/Trademarks/Trade Secrets
  • **WHO OWNS IT?** -- Proprietary or multi-party invention?
  • **WHAT DOES IT INCLUDE?** -- Any 3rd-party licensed IP?
  • **WHAT DOES IT DO?** -- Does it diagnose or treat?
Who Owns the IP in your TeleHealth Product?

Is all the IP proprietary?

• Was it developed or licensed? Or both?

• Multiple parties in on Original Development?
  • Who contributed what?
  • Future development obligations?
  • Rights of first refusal?
  • Healthcare System/R&D?

• Was it developed under a Grant?
  • Bayh-Dole Act – federal “March-In” rights?

35 U.S.C. § 200-212; Implemented by 37 C.F.R. 401
What does your TeleHealth IP Include? Does it live in the Cloud?

- Does the IP include 3rd-party licensed IP?
  - Plug-ins? Necessary to make the product work?—e.g., Telepresence/Video—*who is responsible for ensuring continuation of operation?*
  
  - Informational? Adds info to the product?—e.g., animations/illustrations—*who is responsible for accuracy of information?*

- Is the platform Cloud-based?
  
  - Service Level Obligations of Cloud-hosting company
  - Insurance/Indemnification—Business Associates Agreement (BAA)
What does your TeleHealth IP do?

• Does it DIAGNOSE or TREAT?

• FDA Classification

• Contracts – Indemnification and Disclaimers
  • Contract w/3rd Party IP vendor
    • “Ability to alter content” could be used to place liability on App for mistakes in 3rd party content
  • Contract w/Customer
    • Disclaim liability for diagnosis & treatment if App is information aggregator/facilitator
    • EULA – but also in customer Pilot and/or License Agreement
Telemedicine/mHealth Customer Contracts

- **Pilot Program Agreements**
  - May help get in the door
  - Tie success of program to future purchase
  - May have to use hospital-standard vendor testing agreement
    - *Key – make sure not to give away the IP, keep all necessary disclaimers, get commitment to purchase if measurable milestones are hit*

- **License Agreement**
  - Sold as software only – use any device?
    - *Disclaim for any defects in device or use of device*
  - Include terms of EULA
Telemedicine/mHealth Customer Contracts

Final thoughts:

✓ IP Guides the Drafting

✓ Look At Compliance For Direction Towards Innovation

✓ Be Flexible to Adjust-Customer is King
QUESTIONS & ANSWERS

THANK YOU FOR PARTICIPATING! PLEASE CONNECT WITH US ON LINKEDIN!

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