

## Digital, Mobile, and Virtual Medicine: Legal Challenges

Protecting Patient Privacy, Avoiding Corporate Practice of Medicine, and Ensuring Quality of Care

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# Digital, Mobile, and Virtual Medicine

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# Today's Presentation

- Introductions
- Virtual Medicine
  - Business Model
  - Legal Issues
  - Best Practices
- mHealth
  - Business Model
  - Legal Issues
  - Best Practices
- Q&A

# Convenience Care

- Consumer-driven demand for accessible, affordable, quality health care
- Convenience Care
  - retail clinics
  - virtual medicine
    - traditional telemedicine
    - online consultations
  - mHealth (mobile apps)
- Many Common Legal Issues
- Evolving Regulatory Landscape

# Online Visits Business Model

- Online Diagnosis, Treatment, and Prescriptions



# Online Visits: Legal and Regulatory Issues

- Federal and State Privacy Laws
- Scope of Practice
  - supervision/collaboration requirements
- Prescriptive Authority
- Corporate Practice of Medicine
- Malpractice Risk
- Reimbursement
- Fraud & Abuse

# Online Visits

## Privacy and Security

- HIPAA's Applicability
  - Covered Entities
  - Business Associates
- Protected Health Information
  - Individually identifiable information (written, electronic, or oral) created or received by a provider;
  - Relating to an individual's health, the provision of health care to an individual, or the payment for health care;
  - That identifies the individual or provides a reasonable basis to identify the individual.

# Online Visits

## Privacy and Security

- HIPAA Security Rule

Requires implementation of administrative, physical, and technical safeguards to protect electronic PHI

Covered entities and business associates must:

- Ensure the confidentiality, integrity and availability of all ePHI that it creates, receives, maintains or transmits.
- Protect against any reasonably anticipated threats or hazards to the security or integrity of ePHI
- Protect against any reasonably anticipated impermissible uses or disclosures of ePHI
- Ensure compliance by all workforce members.

# Online Visits

## Privacy and Security

- Consider the following:
  - Organization size, complexity, and capabilities
  - Organization's technical infrastructure, hardware, and software security capabilities
  - Costs of security measures
  - Probability and criticality of potential risks to ePHI
- Examples:
  - Encryption
  - User authentication
  - Secure networks

# Online Visits

## Privacy and Security

- HIPAA Privacy Rule
  - Prohibits uses or disclosures of PHI that are not permitted by the Privacy Rule
  - Marketing is prohibited without patient's authorization
- What is "marketing?"
  - a communication about a product or service that encourages recipients of the communication to purchase or use the product or service

# Online Visits

## Privacy and Security

- Exceptions to marketing definition
  - Communications for the treatment of an individual by a health care provider or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual
    - unless the covered entity receives financial remuneration in exchange for making the communication

# Online Visits

## Privacy and Security

- Exceptions to marketing definition (cont.)
  - Communications to describe a health-related product or service that is provided by or included in a plan of benefits of the covered entity
    - unless the entity receives financial remuneration in exchange for making the communication
  - Refill reminders

# Online Visits

## Scope of Practice/ Prescriptive Authority

- MDs v. NPs v. RNs v. PAs
- Physician supervision rules
  - written collaborative agreement
  - protocols
  - on-site requirements
  - ratios



# Online Visits Scope of Practice/ Prescriptive Authority

- Telemedicine
  - Nurse Licensure Compact
  - consultation exceptions

# Online Visits

## Prescriptive Authority

- Legislative/Regulatory History
- Requirements
  - face-to-face
  - existing patient relationships
- Strategies
- Future
  - push to clarify requirements/change law and accommodate online consultations

# Online Visits

## Corporate Practice of Medicine ("CPM") Prohibition

- CPM doctrine prohibits business corporations from employing medical professionals or owning/controlling medical practices
- CPM prohibition has been criticized by many scholars

# Online Visits

## CPM Violations

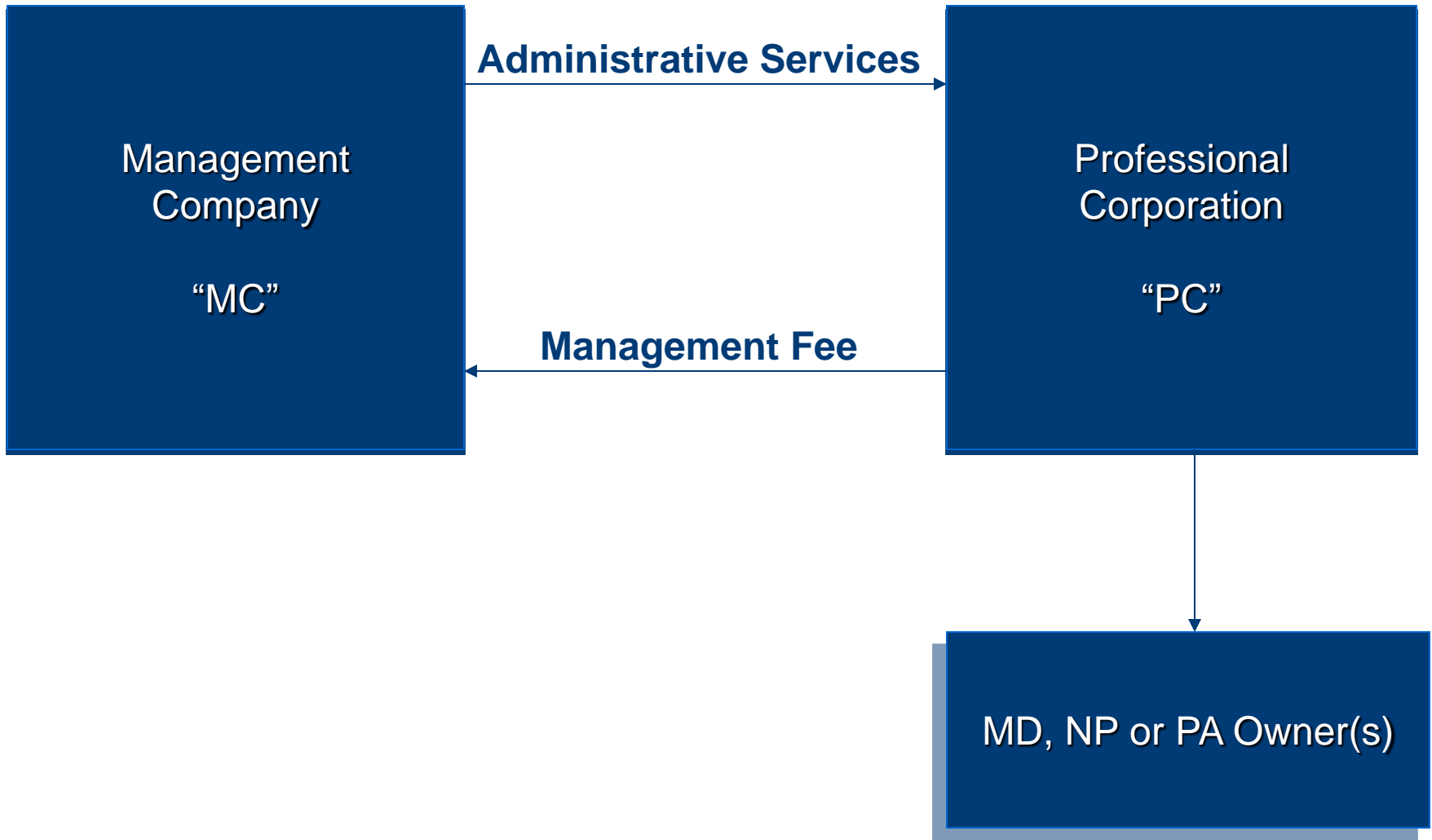
### ■ Potential Ramifications

- refusal to pay claims
- injunction against continued operation of clinic
- criminal prosecution for engaging in the unauthorized practice of medicine
- entire arrangement could be declared void
- technical violation of certain fraud and abuse laws (e.g., the False Claims Act) by virtue of submitting claims to Medicare or Medicaid
- loss of “private practice”, “physician office” and similar exceptions from state licensing requirements (CON, lab license, etc.)

# Online Visits

## CPM Solutions

- If state CPM prohibition applies to structure, the management company model may be an option.



# Online Visits CPM Solutions

- Management Agreement
  - long-term
  - restrictions on termination
  - restrictive covenant
  - management fee
  - management company can handle all non-clinical matters

# Online Visits CPM Solutions

- Risks with management company structure
  - owners may seek to void the agreement
  - may be viewed as a sham
  - licensing boards



# Online Visits Fee-Splitting

- Many States Prohibit Fee-Splitting
  - perceived danger of allowing professionals and non-professionals to share in income from professional services
    - the temptation for the health care professional and nonprofessional to maximize profit through medically unnecessary services
    - temptation for the health care professional and the non-professional to limit medically necessary services in order to maximize income

# Online Visits

## Federal Anti-Kickback Statute

- Prohibits the offering, paying, soliciting or receiving any remuneration in return for
  - business for which payment may be made under a federal health care program; or
  - inducing purchases, leases, orders or arranging for any good or service or item paid for by a federal health care program
- Remuneration includes kickbacks, bribes and rebates, cash or in kind, direct or indirect.

# Online Visits

## AKS (cont.)

- Criminal and Civil Penalties
- Imprisonment
- Civil Monetary Penalties
- False Claims Act exposure

# Online Visits AKS (cont.)

- Relationships requiring AKS analysis
  - relationship with supervising/collaborating physicians
  - relationship with others (management company, etc.)

# Online Visits

## AKS (cont.)

- no issue if federal health care programs are not involved.
  - but remember state anti-kickback prohibitions
- safe harbor protection
- advisory opinions

# Online Visits

## Self-Referral Prohibitions

- The Stark law prohibits a physician from making a referral for certain designated health services (“DHS”) to an entity with which the physician (or an immediate family member) has a financial relationship, unless one of its many exceptions applies
- Stark also prohibits entities from submitting claims for DHS provided pursuant to a prohibited referral

# Stark (cont.)

- Stark is a strict liability statute, meaning that the intent of the parties is irrelevant for purposes of determining whether the law has been violated
- Stark provides for monetary penalties and requires the refund of amounts paid for illegally referred DHS

# Online Visits

## Malpractice Risks

- Telemedicine/Online Consultations
  - What is the standard of care?
  - One example: Hageseth v. The Superior Court of San Mateo County, 59 Cal. Rptr.3d 385 (Cal. Ct. App. 2007).



# Online Visits

## Risk Management

- Risk Management
  - peer review
    - robust physician supervision/chart review
  - monitor developments in clinical practice guidelines
    - use evidence-based treatment guidelines
  - check with insurance carrier
  - limit scope of practice/services offered online
  - address continuity of care

# Online Visits Reimbursement

- Employers and Individuals
- Private/Commercial Payors
- Government Payors
  - Medicare
  - Medicaid
  - other

# mHealth

- What is mHealth?
  - use of diagnostic apps on mobile devices (PDAs, tablets, Google Glass, etc.)
- Use of apps increasing
- Regulatory landscape is evolving
  - FDA Guidance
  - Congressional Hearings

# mHealth

## Food and Drug Administration ("FDA")

### ■ Background

- FDA regulates "medical devices"
  - broad definition
- some mobile apps fit definition of "medical device"
- 2011 Guidance
- Recent Congressional Hearings

# mHealth

## FDA Position

- Recognizes value of mobile apps
- Predicts 500 million users worldwide by 2015
  - and 3.4 billion downloads by 2018!
  - believes it is important to adopt a “balanced approach to mobile medical apps that supports continued innovation, assuring appropriate patient protections”
  - manufacturers need a clear, predictable, and reasonable understanding of FDA’s expectations

# mHealth

## FDA Position

- Reviewed approximately 100 mobile medical apps
  - remote blood pressure, heart rhythm, patient monitors, smartphone-based ultrasounds, EKG machines, and glucose monitors

# mHealth

## 2011 Draft Guidance

### Definitions

- *"mobile platforms"*
  - commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature
    - examples: smart phones, tablet computers, and PDAs

# mHealth

## Definitions (cont.)

- “*mobile application*” or “mobile app”
  - “software application that can be executed (run) on a mobile platform, or a web-based software application that is tailored to a mobile platform but is executed on a server”



# mHealth

## Definitions (cont.)

- “*mobile medical application*” or “mobile medical app” meets the definition of a “device” if it:
  - (a) “is used as an accessory to a regulated medical device”; or
  - (b) “transforms a mobile platform into a regulated medical device.”

# mHealth

## Regulated Product?

- whether a product is a mobile medical app depends on its intended use
  - intent is everything

# mHealth

## Excluded Apps

- electronic textbooks or references
- general health and wellness mobile apps
- office administration mobile apps
- generic aids
- electronic or personal health records

# mHealth Regulated Entities

- Manufacturers
- Does not include app distributors  
Android Market, iTunes Store, and  
BlackBerry App World.

# mHealth Privacy Laws

- HIPAA
- State laws
- State consumer protection laws
  - Ex. California

# mHealth

## Federal Advertising Laws

- Federal Trade Commission
  - FTC consumer protection law prohibits unfair or deceptive trade practices
    - applies to all mobile apps
- enforcement actions
  - Cheerios Letter
  - acne case

# mHealth

## Federal Advertising Laws

- FTC Recommendations
  - incorporate privacy protections into standard business practices
  - provide customers with simpler privacy options
  - increase transparency of data practices to consumers

# mHealth

## State Advertising Laws

- Professional Licensure Requirements
- State Consumer Protection Laws
  
- Remember: HIPAA and similar state laws



# mHealth Licensing & Prescriptive Authority

- Face-to-face requirements
- Established patient relationship
- Scope of Practice
  - collaboration/supervision requirements, etc.

# mHealth Malpractice

- Negligent Use
- Negligent Referral
- Risk Management
  - providers
    - prohibit use of apps
    - restrict use of apps to pre-approved list
    - other
  - app developers
    - disclaimers

# mHealth Reimbursement

- Evolving landscape

# mHealth Fraud and Abuse

- AKS
- Fee-Splitting
- Self-Referral Prohibitions

# mHealth

## Practice of Medicine?

- Questions
  - What constitutes practice of medicine?
  - Medical/nursing board position?
  - CPM
  - Unauthorized practice of medicine

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