Telemedicine
Healthcare market changes and emerging compliance risks

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Objectives

Provide a description of current healthcare market changes in the United States, and how these will influence the rapid scaling and deployment of telemedicine into novel healthcare settings.

Describe the current reimbursement landscape and recognize areas for growth.

Identify regulatory and compliance challenges for telemedicine deployments, including information security and privacy obligations, scope of practice restrictions, and corporate practice of medicine prohibitions

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Telemedicine and Medicare: Starting in 2001

Consultation, office visits, individual psychotherapy, and pharmacologic management

"An interactive telecommunications system is required as a condition of payment.." with the exception of demonstration programs in two states

"Eligible geographic areas include rural health professional shortage areas (HPSA) and counties not classified as a metropolitan statistical area (MSA)"

"…payment for the professional service performed by the distant site practitioner (i.e., where the expert physician or practitioner is physically located at time of telemedicine encounter) is equal to what would have been paid without the use of telemedicine."

Source: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

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Medicare originating sites

"Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in either a rural health professional shortage area …. or in a county outside of an MSA.."

"The term originating site means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs."

"… geographic eligibility for an originating site is established for each calendar year based upon the status of the area as of December 31st of the prior calendar year."

Source: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf

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Medicaid and telemedicine: a patchwork

"…. states have the option/flexibility to determine whether (or not) to cover telemedicine; what types of telemedicine to cover; where in the state it can be covered; how it is provided/covered; what types of telemedicine practitioners/providers may be covered/reimbursed, as long as such practitioners/providers are "recognized" and qualified according to Medicaid statute/regulation; and how much to reimburse for telemedicine services, as long as such payments do not exceed Federal Upper Limits."

Source: https://www.medicaid.gov/medicaid/benefits/telemed/index.html

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State policies and laws are rapidly changing

An excellent 2015 summary was produced by the National Conference of State Legislature, and is available at http://www.ncsl.org/documents/health/telehealth2015.pdf

Many states are legislating parity for telemedicine services

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Provider licensing

Proposed federal legislation for Medicare and VA patients for physician licensing

Proposed telemedicine licensing compact by the Federation of State Medical Boards for physician licensing

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Employer health plans

Many employers are adding telemedicine benefits to health plans, due to decreased expense compared to office visits

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Healthcare Trends: Patients

- Patients are redefining healthcare delivery by demanding services in a consumer-centric rather than physician-centric manner.

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Healthcare Trends: Clinicians

- Greater practice management complexity will drive changes in employment model preferences.
- Physician shortages will drive acceptance of technology-enabled care delivery and broader use of advanced practice clinicians.

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Healthcare Trends: Payers

- Many payers will consolidate.
- All payers will increase the portion of reimbursement flowing through value-based payment arrangements.

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Healthcare Trends: Hospitals

- Hospitals will generally consolidate into larger systems, expand into the post-acute space and seek more effective strategies for the management of acquired or affiliated physician practices.

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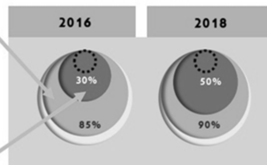
Healthcare Trends: Post-acute Care

- Payer value-based reimbursement arrangements will incent both physicians and hospitals to actively manage the costs of post-acute care.

The new Merit-based Incentive Payment System helps to link **fee-for-service payments** to quality and value.

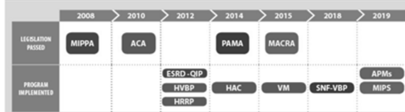
The law also provides incentives for **participation in Alternative Payment Models** in general and bonus payments to those in the most highly advanced APMs



- **All** Medicare fee-for-service (FFS) payments (Categories 1-4)
- Medicare **FFS** payments **linked to quality and value** (Categories 2-4)
- Medicare payments linked to quality and value **via APMs** (Categories 3-4)
- **Medicare Payments to those in the most highly advanced APMs under MACRA**

Source: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-LAN-PPT.pdf

VALUE-BASED PROGRAMS



LEGISLATION
- **ACA:** Affordable Care Act
- **MACRA:** the Medicare Access & CHIP Reauthorization Act of 2015
- **MIPPA:** Medicare Improvements for Patients & Providers Act
- **PAMA:** Protecting Access to Medicare Act

PROGRAM
- **APMs:** Alternative Payment Models
- **ESRD-QIP:** End-Stage Renal Disease Quality Incentive Program
- **HACRP:** Hospital-Acquired Condition Reduction Program
- **HRRP:** Hospital Readmissions Reduction Program
- **HVBP:** Hospital Value-Based Purchasing Program
- **MIPS:** Merit-Based Incentive Payment System
- **VM:** Value Modifier or Physician Value-Based Modifier (PVBM)
- **SNFVBP:** Skilled Nursing Facility Value-Based Purchasing Program

Source: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html

Episode of care accountability models create Physician, Hospital, and Post-Acute alignment

In 2017, under the Quality Payment Program, clinicians may earn a 5 percent incentive payment through participation in the following Advanced APMs:

In 2018, we anticipate that clinicians may earn the incentive payment through participation in the following additional APMs:

Source: https://qpp.cms.gov/docs/Quality_Payment_Program_Overview_Fact_Sheet.pdf

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Waivers of patient incentives, geographic and location restrictions

- Waiver for Patient Engagement Incentives Provided by Participant Hospitals to Medicare Beneficiaries in CJR Episodes
  "…technology in the form of a device to monitor and transmit medical indications and symptoms could be reasonably related to medical care provided during an Episode…"
- Telehealth waiver
  "Under CJR, CMS will allow a beneficiary in a CJR episode in any geographic area to receive services via telehealth. CMS also will allow a home or place of residence to be an
  originating site for beneficiaries in a CJR episode. This will allow payment of claims for telehealth services delivered to beneficiaries at eligible originating sites or at their residence,
  regardless of the geographic location of the beneficiary.
- Similar waivers for Next Generation ACOs & Bundled Payments for Care Improvement Initiate (BPCI)

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HIPAA

- HIPAA refers to the Health Insurance Portability and Accountability Act of 1996
- Impacts covered entities and business associates of covered entities
- HITECH Act enacted February 17, 2009
- Strengthened privacy and security protections and enhanced penalty provisions
- HIPAA Final Omnibus Rule issued January 25, 2013

Civil Penalties

- Did not know (even with diligence)- minimum of $100 per violation
- Reasonable Cause- minimum of $1,000 per violation
- Willful Neglect; violation cured- minimum of $10,000 per violation (if corrected; if not, $50,000)
- For all types: Up to $1,500,000 per year for multiple violations of the same part of HIPAA

Criminal Enforcement

- Criminal penalties can be imposed not only on covered entities and business associates but also on individual employees who obtain or disclose PHI without authorization
- Range of penalties
  - from $50,000 plus one year imprisonment for knowingly violating HIPAA; to
  - $250,000 plus ten years' imprisonment for doing so with intent to profit by or do harm with the information

HIPAA: Implications for Telemedicine Privacy Rule

- Authorization: when do you need it?
  - Treatment exception
  - Obtain authorization when required
  - OCR guidance on "duty to warn"
- Safeguards
- Individual rights
  - Accounting of disclosures
  - Access
  - Amendment
  - Privacy Notice

HIPAA: Implications for Telemedicine Privacy Rule (cont'd)

- Business associate relationships
  - Review of server, software and cloud vendors
  - "Mere conduit" exception
  - Recent OCR enforcement actions: are your BAAs up to date?
- Auditing your telemedicine vendors

HIPAA: Implications for Telemedicine Security Rule

"[I]f the covered entity… is planning to incorporate new technology to make operations more efficient, the potential risk should be analyzed to ensure the ePHI is reasonably and appropriately protected. If it is determined that existing security measures are not sufficient to protect against the risks associated with the… introduction of new technology, then the entity must determine if additional security measures are needed."

Office for Civil Rights
July 14, 2010

HIPAA: Implications for Telemedicine Security Rule (cont'd)

- Administrative safeguards
  - Information system activity review
  - Security Awareness and training
  - Incident investigation and reporting
- Physical safeguards
  - Are appropriate device and workstation controls in place?
- Technical safeguards
  - Is encryption reasonable and appropriate?

HIPAA: Implications for Telemedicine Breach Notification Rule

- Increased risk of exposure
  - If not secure connection, notification required
- Implications of breach reporting
  - Have you documented a risk analysis?
  - Have you implemented reasonable and appropriate safeguards?
  - Are you exercising oversight of your vendors?

The Corporate Practice of Medicine Doctrine

- Prohibits a lay corporation from owning an interest in a medical practice or employing physicians
  - ❖Intended to prevent non-clinicians from interfering with professional medical judgment
- Established by statute and/or developed at common law
  - ❖States vary greatly with respect to the degree of enforcement, scope of exceptions, etc.

Issues

- Restriction on ability to provide opinions/advice remotely?
  - Interference with physician/patient relationship?
  - Selection of equipment, vendors
  - Management function
- May require physicians to be affiliated with or employed by a professional corporation in each of the states where they "practice medicine"
  - Logistical, contracting issues may arise
  - CPOM more likely to be enforced through contract disputes, though government enforcement is possible

Compliance with CPOM in Telemedicine

- Know the lay of the land

- When practicing medicine across state lines, may need to restructure operations
  - Friendly PC maintains control over clinical decisions
  - Management Services Organization maintains control over financial and management affairs

- State licensure and PC requirements
  - Consider how state licensure requirements may impact the friendly PC structure

Scope of practice/licensure

- What is the scope?
  - Consult, visit, prescribe etc.
  - Know the exceptions and limitations
    - E.g. consultation exception in Tennessee
- In-person visit requirements
  - State law hurdles

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The Federal Anti Kickback Statute

"The anti-kickback statute **prohibits in the health care industry some practices that are common in other business sectors**, such as offering gifts to reward past or potential new referrals."

See OIG Supplemental Compliance Guidance for Hospitals, 70 FR at 4861 (Jan. 31, 2005)

Federal Anti Kickback Statute
42 U.S.C. § 1320a-7b(b)

- Criminal offense to knowingly and willingly offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by a federal health care program (i.e., Medicare, Medicaid, TennCare, TRICARE)
- Liability on both sides of "kickback" transaction
- It is the OIG's position that this statute prohibits any arrangement where one purpose of the remuneration is to induce referrals
- "Remuneration" includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly

Caution!

Almost
Any
Benefit
by and between
Medical Providers
can be considered
"Remuneration"

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Anti Kickback Statute

- Criminal and civil penalties
- $25,000 per offense
- Imprisonment up to 5 years
- Civil monetary penalties (exclusion and $50,000)
- Exclusion
- Possible False Claims Act liability

Hypothetical: Proposed telemedicine network for acute stroke care

Facts

- Hospital has nationally ranked neuroscience program ("hub")
- Community hospitals frequently transfer stroke patients to facilities with specialized capabilities to treat these patients
- Treatment most effective when begun in ER
- Hub hospital seeks to create a network of affiliated community hospitals ("spokes") to provide immediate consultations

Hypothetical: Proposed telemedicine network for acute stroke care

Facts

- Hub hospital offers to spoke hospitals, at no charge:
  - Neuro emergency telemedicine technology
  - Clinical consultations via telemedicine
  - Clinical protocols
- Hub hospital accepts acute stroke transfers from spoke hospitals
- Hub hospital bills 3rd party payors for consults when permissible
- Spokes agree to period of exclusivity

Hypothetical: Proposed telemedicine network for acute stroke care

OIG's Concerns

- Gifts to potential referral sources with independent value
  - Inducement to refer patients
- "Swapping"
- Increased costs to federal health care programs

Does the Arrangement Meet a Safe Harbor?

1 Space rental

2 Equipment rental

3 Personal services and management contracts

4 Bona fide employees

5 Electronic prescribing

6 Donation of EHR technology

OIG's Analysis

- Unlikely to generate appreciable referrals
  - Intended to *reduce* transfers to stroke center
  - No additional compensation to emergency physicians
  - Participating hospitals not required to refer patients to the stroke center
- Volume or value of referrals is not a condition to participation in network
  - Initially, program offered only to hospitals with preexisting affiliation
  - Expanded only based on demonstrated need

OIG's Analysis (cont'd)

- Primary beneficiaries are stroke patients who can be treated in spoke hospital's ER
  - Participating hospitals pay their own way for staffing, operational and maintenance costs
  - Distinguished "educational offerings" from CME courses provided for free
- Each party responsible for marketing
- Low likelihood of increased costs to Medicare program

Federal Stark Law

- Prohibits a **physician** from
  - **Referring** a patient
  - To an **entity** in which the physician (or **an immediate family member**) has a **financial relationship** (ownership or compensation)
  - For the furnishing of **designated health services**
  - Otherwise payable by Medicare/Medicaid
- unless a specific exception is met

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Penalties

- Strict liability statute
- Penalties include:
  - Civil monetary penalties (up to $15,000 for each prohibited referral) (up to $100,000 for a circumvention scheme)
  - Exclusion from participating in Medicare/Medicaid programs
  - Denial of payment for services provided
  - Refunds of amounts collected
  - Self-Referral Disclosure Protocol

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The Stark Law: Consequences

- If a physician makes a referral for DHS in violation of the Stark Law, the entity receiving the referral cannot bill Medicare or Medicaid for services provided pursuant to that referral.
- If the entity knows that a referral violated the Stark Law and received payment for that service, the entity must refund the payment.
- If the entity knowingly fails to refund the payment for 60 days, the entity may be liable under the False Claims Act for treble and statutory damages on each claim submitted.

Does the Arrangement Meet a Financial Relationship Exception?

1. **Community-wide health information systems**
2. **Rental of office space/equipment**
3. **EHR items and services**
4. **Personal services arrangements**
5. **In-Office Ancillary Services**
6. **Ownership of a rural provider**

Avoiding Stark Law Risks In Telemedicine Arrangements

- Understand how Stark applies
  - Strict liability
  - More limited in scope than the AKS
    - Physicians
    - DHS
- Referral from originating site to distant site (or vice versa)
- Identify financial relationships
  - Ownership interest
  - Compensation arrangement
  - *Indirect relationships?*
- Structure to meet an exception