DIGITAL HEALTH AND TELEMEDICINE:
A National Perspective

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Agenda

- Introduction
  - Defining Digital Health
  - Global Perspective on Potential Value Proposition
- Telemedicine Reimbursement
- New Payment Models – Value Opportunities
- State Issues
- Digital Health Technology Development and Deployment
Introduction
Introduction: *Defining Digital Health*

**Telemedicine**

**Big Data**

**EHR and Health IT**

**Consumer Tools**
**Introduction: Defining Digital Health**

**Telemedicine**: “the use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical health status.”*  
- Generally involves a provider to patient or provider to provider encounter.  
- Telemedicine is a tool in the delivery of care – it is **NOT** a separate medical specialty.  
- Examples include telestroke, second opinion, direct-to-consumer programs.

**Big Data**: the use of large amounts of data and appropriate analytic tools to identify health trends in populations, more effective treatment options and other improvements in care delivery  
- Big data tools rely on the collection of large amounts of data and the development of effective analytics tools.  
- Big data tools are rarely direct-to-consumer; rather, they assist health care providers and managed care organizations to improve their offerings.

*American Telemedicine Association, available at:  
Introduction: *Defining Digital Health*

**Consumer Health Tools**: products and services used by consumers to obtain health information, manage and improve their health, and intelligently choose and access health care solutions.

- Consumer health tools include mobile medical apps, and specialty devices to capture, store and communicate information.
- Consumer health tools also include on-line scheduling, on-line provider reviews and nutrition and weight-loss tools.

**EHR and Health IT**: products and services used by providers and consumers to collect and communicate a patient’s medical information.

- Traditional EHR tools and patient portals, but also other types of tools that enable providers to communicate medical information.
- Examples include computerized alerts, reminder systems to notify patients about preventative or follow-up care, and prompts to provide patients with test results.
Introduction: Defining Digital Health – Today and Tomorrow

- The digital health tools of today will look very different from the telehealth tools of tomorrow due to innovation in:
  - Technologies
  - Care delivery models
  - Consumer awareness and demand
  - Coverage and reimbursement
  - Other areas
Introduction: Digital Health’s Potential Value Proposition – Payment in Transition

Fee For Service

- Reward unit cost
- Limited focus on care efficiency and patient centeredness
- Limited alignment with quality
- Siloed practitioners & isolated patients
- Focus on “cures and treatments”

New Payment Models

- Reward health outcomes
- Lower cost, improve patient experience
- Improve quality, safety and access
- Physician and patient engagement
- Focus on total patient “health”
Introduction: Digital Health’s Potential Value Proposition – Demand for Change

- Self Pay
- Government Programs
  - Medicare
  - Medicare Advantage
  - Medicaid
  - Medicaid MCOs
- Commercial Payors
  - Insurance
  - Employer Plans

Increasingly demanding risk sharing, higher quality and greater efficiency

New Payment Models
Introduction: Digital Health’s Potential Value Proposition – Demand for Change

Example: CMS Taxonomy of Payment Reform

Category 1: Fee for Service; No Quality Link

Category 2: Fee for Service; Quality Link

Category 3: Alternative Payment Models Built on Fee-for-Service Architecture

Category 4: Population-Based Payment

- Limited; majority of Medicare payments now linked to quality
- Hospital VBP
- Physician VBM
- Readmissions, Acquired Condition Programs

- ACOs (MSSP, Pioneer, CEC)
- Medical homes (CPC, MAPCP)
- Bundled payments (BPCI, OCM, CJR)

- Eligible Pioneer ACOs (Yrs 3-5)
- Next Generation ACO Model (PBP and capitation)
- Maryland All-Payer Model

By 2016: 85% FFS payments tied to quality and value | 2018: 90%

End of 2016: 30% FFS payments in APMs | End of 2018: 50%
Introduction: *Digital Health’s Potential Value Proposition?*
## Introduction: Digital Health’s Potential Value Proposition

<table>
<thead>
<tr>
<th>Access</th>
<th>Quality</th>
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<tbody>
<tr>
<td>• Reduces ER visits</td>
<td>• Needed specialties at the right time</td>
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<tr>
<td>• Access to needed specialists</td>
<td>• Greater connectivity between patients and provider</td>
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<tr>
<td>• Access for isolated patient populations</td>
<td>• Better manage chronic conditions</td>
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<table>
<thead>
<tr>
<th>Cost</th>
<th>Service</th>
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<tbody>
<tr>
<td>• Can be lower cost option</td>
<td>• Better communication between provider and patient</td>
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<tr>
<td>• Long-term value (chronic conditions)</td>
<td>• Consumer empowerment and control</td>
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<td>• More and better information to drive diagnosis and treatment decisions</td>
<td>• Care when and where wanted</td>
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Telemedicine Reimbursement
## Reimbursement: Expansion

<table>
<thead>
<tr>
<th>Medicare</th>
<th>Medicaid</th>
<th>Commercial</th>
<th>Self Pay</th>
<th>Payment Reform</th>
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<tr>
<td>• Traditional high barrier to reimbursement</td>
<td>• Experimentation • Scattered and inconsistent requirements for reimbursement</td>
<td>• Initial resistance • Steady expansion of acceptance</td>
<td>• Increased investment by consumers • Direct to consumer and managed care experience creating acceptance • Information technology tools increasing demand</td>
<td>• Benefits of telemedicine and other digital health tools being proven • Direct reimbursement may be elusive, but economic value exists</td>
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**Digital Health and Telemedicine: A National Perspective**
Reimbursement: Medicare

CMS Conditions of Coverage Medicare Reimbursement Requirements (42 C.F.R. § 410.78)

- **Practitioner**
  - Physician, nurse practitioner, clinical psychologist, clinical social worker, etc., and
  - Licensed to furnish the service in the state where the beneficiary is receiving treatment

- **Delivery Method**
  - Delivered via an interactive telecommunications system

- **Originating Site**
  - Physician office, critical access hospital, rural health clinic, hospital, skilled nursing facility, etc., and
  - Located in a rural health professional shortage area or in a county not included in a Metropolitan Statistical Area
Reimbursement: Medicare

Reimbursement to Distant Provider and Originating Site

Reimbursement to the health professional = same as the current fee schedule.

Originating Site is eligible to receive a facility fee (does not include patient’s home).

Use appropriate CPT code for the service and the telemedicine modifier “GT”
The ~14 million beneficiaries in Medicare Advantage (MA) plans have flexibility in using telemedicine - as long as their provider offers the service.

Currently, Humana, Anthem and the University of Pittsburgh Medical Center Health Plan offer telemedicine to MA beneficiaries.
Reimbursement: Medicaid

48 states have some form of public reimbursement for telemedicine services

- Usually no geographical restriction (like Medicare) – but may limit eligible provider and facility types
- Live video most reimbursed form (RPM and store and forward reimbursed in a much smaller number of states)
Reimbursement: *Commercial Payers*

- Policy and approach varies from payer to payer
- More than half of the states have adopted laws that **require** private insurers to cover and/or reimburse providers for certain telemedicine services.
- These laws are referred to as “Telemedicine Payment and/or Coverage Parity Laws”.
Reimbursement: Commercial Payers – Coverage Parity Laws

Require plans to cover telemedicine to the same extent the plan covers the services if provided through an in-person visit.

- Do not mandate the health plan develop or provide new service lines or specialties
- Scope of services in the member benefit package remain unchanged
- Frequently include language to protect patients from cost-shifting
  - Prohibits health plans from imposing different co-pays, deductible or maximum benefit caps for telemedicine services

Digital Health and Telemedicine: A National Perspective
Reimbursement: *Commercial Payers – Payment Parity Laws*

Require plans to pay for telemedicine at the *same or equivalent rate* the plan pays the provider when the service is provided in-person.

- For example, if a plan pays $100 for each patient examination, the plan must pay the same or equivalent rate regardless of whether provided in-person or via telemedicine.
- Doctor’s services must still be appropriately documented and medically necessary in order to be paid.
- Do not (nor are they intended to) hinder opportunities for cost savings opportunities.
- Plans and providers may still voluntarily contract for APMs.
Reimbursement: *Commercial Payers – “If…. then…”*

- Often of limited utility, but better than nothing
- Example: Illinois: **If** a policy of accident or health insurance provides coverage for telehealth services, **then** it must comply with certain prohibitions (e.g., can’t require in-person contact for services to be provided through telehealth, can’t require use of telehealth if provider has determined not appropriate, etc.).
Consider the following when reviewing telemedicine payment and/or Coverage Parity Laws:

- Does the law cover services provided via telehealth to the same or a lesser extent than in-person services?
- Does the law limit the technologies used?
  - Does it cover interactive services only OR additional telehealth-based services?
- Does the law include other restrictions that limit its effectiveness and usefulness to telehealth providers?
Reimbursement: Self-Pay

Why popular:

• Patients increasingly investing time and money into improving their health, and seek convenience
• High deductible health plans

Considerations:

• Medicare assignment rules, which require Medicare enrolled physicians to accept payment from the Medicare program
  • Even if the service is not covered by Medicare, consider providing a patient who is or likely to be a Medicare beneficiary with a notice of non-coverage (ABN) to sign before the service is rendered.
• Whether the provider is in network with the patient’s commercial health benefit plan to determine if there are any applicable benefit assignment provisions in the payor’s contract.
  • Some payor contracts prohibit direct billing, especially for in-network providers.
• State laws and regulations related to the direct billing of insureds in certain kinds of plans
New Payment Models – Value Opportunities
New Payment Models: *Value Opportunities*

- Direct Reimbursement
- Digital Health
- Revenue Enhancement / Protection

Digital Health and Telemedicine: A National Perspective
New Payment Models: *Value Opportunities*

- MACRA
- Chronic Disease Working Group
- CHIP/MMC
- CONNECT for Health
- Maryland All-Payer Model
New Payment Models: MACRA

Pre-MACRA
- Uncertainty over annual SGR update
- FFS dominant payment method
- Multiple disconnected physician quality programs

Post-MACRA
- Period of stable payments
- Increased portion of payment at risk
- Consolidation of various physician quality programs into one program

Clinicians must choose to participate in Merit-Based Incentive Payment (MIPS) or certain Alternative Payment Models (APM)

MACRA fundamentally changes Medicare physician payment.
Clinician compensation under MIPS is evaluated under multiple categories.

One category is “Clinical Practice Improvement Activities” (CPIA).

CPIA includes care coordination, “such as . . . . use of remote monitoring and telehealth.”*

*§101(c)(2)(B)(iii)(III)

APMs are highly evolved, specific programs (including ACOs).

Requirements of APMs can be specific.

But: MACRA does not prohibit APM from including non-reimbursed telehealth services.*

*§101(z)(5)
New Payment Models: **MACRA – General Support of Digital Health Value Proposition**

**MIPS and APMs** are designed to incentivize efficiency and quality.

**Digital health tools** can help providers achieve efficiency and quality and provide value regardless of direct reimbursement.
New Payment Models: *Chronic Disease Working Group*

- On December 18, 2015, the Senate Committee on Finance released a Bipartisan Chronic Care Working Group Policy Options Document.

- Document proposes:
  - Increasing digital health for MA *and* permitting MA plans to include certain telehealth services in their annual bid amounts
  - Waiving geographic location requirements for Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP) ACOs in two-sided risk models
  - Remote patient monitoring in ACOs
  - Telestroke and end-stage renal disease (ERSD) services.
New Payment Models: *Medicaid and Children’s Health Insurance Programs (CHIP) Final Rule*

**Key Provisions**
- Focuses on network adequacy standards - both in terms of state responsibilities and Medicaid managed care plans - and advises states to contemplate telemedicine, e-visits, and/or other evolving and innovative technological solutions.
- Suggests that telemedicine should be incorporated to meet network adequacy standards in the context of Medicaid managed care.
- Aligns with the separate CMS Rule from 2015.

**Why it Matters**
- National Association of Insurance Commissioners released proposed model legislation for states that also includes telemedicine as a way to meet network adequacy standards.
- CHIP Final Rule and NAIC Model legislation illustrate a trend toward streamlined efficiency that is reliant on technology remedies a common problem associated with narrow networks: namely, inadequate access to care.
### New Payment Models: CONNECT for Health Act

<table>
<thead>
<tr>
<th>Key Provisions</th>
<th>Potential Impact</th>
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<tbody>
<tr>
<td>Removes certain geographic and payment restrictions for telemedicine (and RPM) services provided to Medicare beneficiaries.</td>
<td>Expected to lower federal spending by $1.8 billion over a 10-year timeframe.</td>
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<tr>
<td>Creates a “bridge” telemedicine demonstration project (expanding providers’ use of telehealth in anticipation of MACRA).</td>
<td>Expected to improve patient access to services.</td>
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<td>Provides payments to APMs for RPM services and expands use of RPM for certain patients with chronic conditions and recent hospitalizations.</td>
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<td>Proposed positive changes to MA plans designed to increase telehealth use.</td>
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New Payment Models: *Maryland All-Payer Model – General Incentives*

Hospitals operate under annual, global budget for all inpatient services for all payers.

Reimbursement model incentivizes care coordination, population-health based strategies to reduce inpatient visits.

Digital health tools can be utilized to achieve better care-coordination, implement population-health based strategies and reduce inpatient visits.
New Payment Models: *Observation on Digital Health Value Over Time*

- Direct Reimbursement
- Revenue Enhancement & Protection
  - MACRA
  - Maryland All Payer
  - ACOs and other Shared Savings
  - Trend – Quality & Efficiency
- Some specific legislation
- Telemedicine
State Issues:
Licensure, Standard of Care, Scope of Practice
Digital Health State Issues

- States have their own:
  - Licensing laws and requirements
  - Standards of care
  - Scope of practice laws, identifying who may provide healthcare services and the scope of such services
  - Other requirements (e.g., consent)
Digital Health State Issues: Licensure

Generally, licensure also required in the state *where the patient is located*

| Full licensure | Special license/Certificate |

Exceptions may exist

| Consults with existing patients | Limited consults | Physician to physician consults |

Efforts to reduce barriers

| Federation of State Medical Boards Interstate Medical License Compact |
Digital Health State Issues: Licensure

- Other licensed health professionals must contend with the same conceptual issues
  - Standards / requirements may be more or less helpful or developed
    - Nurse Compact
Digital Health State Issues: Standard of Care

- General consensus that all treatment provided via telemedicine will be held to the same standard as face-to-face encounters.
  - Some states identify the standard in which care is delivered via telemedicine:
    - May depend on the context (e.g., online).
    - May be limited to prescribing.
Digital Health State Issues: Standard of Care – Open Questions

How is the standard of care impacted by the existence and proliferation of digital health tools?

Will malpractice standards change?

Will ubiquitous consumer utilization change the standard of care?
Digital Health State Issues: Scope of Practice

- Scope of practice especially relevant to
  - Direct to patient arrangements
  - Online second opinions
  - Follow-up visits/consults for existing patients (e.g., mental health, chronic disease)

- Significant variation between states
  - Some states have no additional regulations (above existing standards of care)
  - Others severely restrict when and how telemedicine may be used

- Focus has been on telemedicine
Digital Health State Issues: Scope of Practice & Standard of Care

- Can a physician-patient relationship (not preexisting) be established via telemedicine? When has the relationship been established?

- Is there any requirement for a face-to-face visit prior to delivering care via telemedicine?
  - In-person exam required to establish valid doctor-patient relationship?
  - In-person exam required for diagnosis and treatment recommendation?
  - In-person exam required to prescribe?
    - All medications or just controlled?
    - New prescription or refills?
    - Online interface in real time count?
    - Exceptions if patient present at health facility?

- What supervision requirements are applicable for licensed and unlicensed personnel?

- How do other digital health tools impact these issues?
Digital Health Technology Development and Deployment
Digital Health Development: Overview

- Digital health will be critical to achieving value-based care objectives
  - Data access: collecting, sharing and using data through a technology solution allows:
    - More complex and urgent conditions to be diagnosed and treated
    - Enhanced care coordination
    - Remote monitoring and intervention
- Limitless opportunity for (quality) new development
- Driving increased collaboration between traditional technology companies, healthcare providers, insurers, device manufacturers, pharmaceutical companies and other players
Globally, the digital health market is predicted to grow to $34 billion in 2020. (Mordor Intelligence, 2015).

Domestically, annual investment in “on-demand” health services will quadruple from $250 million to $1 billion by 2017. (Accenture, 2015).

The global internet of things (IoT) healthcare market is expected to grow from $32.47 billion in 2015 to $163.24 billion by 2020 (Markets and Markets, 2015).
Digital Health Technology Development: Preliminary Considerations

- Regulatory Environment
- Intellectual Property Rights
- Deployment Strategies
- Liability Issues
Digital Health Technology Development: Regulatory Considerations

- Health Insurance Portability and Accountability Act (HIPAA)
- Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Federal Trade Commission Act (FTC Act)
- State Laws

Digital Health and Telemedicine: A National Perspective
Digital Health Technology Development: Mobile Health Apps Interactive Tool

Digital Health Technology Development: Mobile Health Apps Interactive Tool

1. Do you create, receive, maintain, or transmit identifiable health information?
   - YES
     - GO TO QUESTION 2 to determine if HIPAA applies.
   - NO

2. Are you a health care provider or health plan?
   - YES
   - NO
     - GO TO QUESTION 3 to see if HIPAA applies.

3. Do consumers need a prescription to access your app?
   - YES
   - NO
     - GO TO QUESTION 4 to see if HIPAA applies.

## Digital Health Technology Development: *Myriad of Intellectual Property Rights in Telehealth Tools*

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<thead>
<tr>
<th>Patents</th>
<th>Copyright</th>
<th>Trade secrets</th>
<th>Trademark rights</th>
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<tbody>
<tr>
<td>• Device specifications</td>
<td>• Software code (object and source code)</td>
<td>• Software code (object and source code)</td>
<td>• Product name</td>
</tr>
<tr>
<td>• Methods of manufacture</td>
<td>• Compilations of data</td>
<td>• Software algorithms</td>
<td>• Taglines</td>
</tr>
<tr>
<td>• Software processes</td>
<td>• Look and feel</td>
<td>• Manufacturing processes</td>
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<tr>
<td></td>
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<td>• Back-end technology</td>
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Digital Health Technology Development: Deployment Strategies

Direct to consumer
• Designed for consumer use but can be used to send data to provider for telemedicine consult

Provider to Patient
• Comprehensive telehealth tools with integrated functionality to collect and deliver data to providers
• IoT devices or mobile apps available by prescription from physician

Provider to Provider
• Tools allow data sharing for remote consultations between providers

What is the revenue model?
Digital Health Technology Development: Revenue Model

- Direct to consumer?
- Reimbursed by third-party payor?
- Utilized to achieve success under APM?
- Who pays for what?

Many technology companies are unfamiliar with the reimbursement / cash-flow infrastructure of health care services.
Digital Health Technology Development: Liability Issues

Potential Liabilities

• Malpractice
• Product liability
• Breaches of privacy and security
• False/deceptive advertising

Risk Mitigation

• Allocate risk among parties given their roles in development/deployment
• For mobile apps, effectively use terms of service and privacy policies.
Terms of Service = legally binding agreement between App publisher and App user.

Provide clear, concise terms that are easily understood by the user.

Establish:
- “Rules of the road” relating to access and use of App
- App capabilities and limitations
- Limits of App publisher’s liability
- Privacy/security obligations and expectations through an incorporated Privacy Policy
- App store required terms.
Digital Health Technology Development: *App Terms of Service - Rules of the Road*

- License to user to access and use App for a specific purposes (e.g., personal or business use)
  - Note that the user rights may be very different for a health care provider and a patient

- App usage rules:
  - Age
  - Prohibited conduct
  - Treatment of passwords
  - Rules for using content included in the App

- Establish data usage rights for App publisher if desired
Courts have generally affirmed App publishers’ rights to include certain important protections provided that clear, unambiguous notice is provided.

Warranty disclaimers:
- App is merely facilitating communications between health care providers and patients and does not itself provide medical advice.
- Patients are encouraged to seek health care provider advice in interpreting information provided by the App.
- Health care providers should ensure they are appropriately licensed.

Limitations of liability:
- App publisher not responsible for indirect, consequential damages.
- App publisher not liability for damages above a specified cap.
Digital Health Technology Development: 
App Privacy Policies

- Privacy Policy should clearly and accurately describe:
  - Who is the data collector (App publisher or health care provider)?
    - Does HIPAA apply?
      - If not, notify patient
  - What/how information is collected:
    - Personal information (name, address, email address or SSN)
    - Protected Health information (PHI)
    - Location data
    - Data from a wearable or other IoT device
Digital Health Technology Development:

App Privacy Policies (cont’d)

- How information is used:
  - To provide services to the user
  - To improve products and services or to develop new products
  - To aggregate and de-identify information for benchmarking and analysis or “for any purpose permitted by law”

- How information is shared:
  - Information sent to providers or interfaced with EHR system
  - Information available to be accessed by other providers on individual’s treatment team
  - Social media sharing
Contact Information

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