

DIGITAL HEALTH AND TELEMEDICINE: A National Perspective

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Agenda

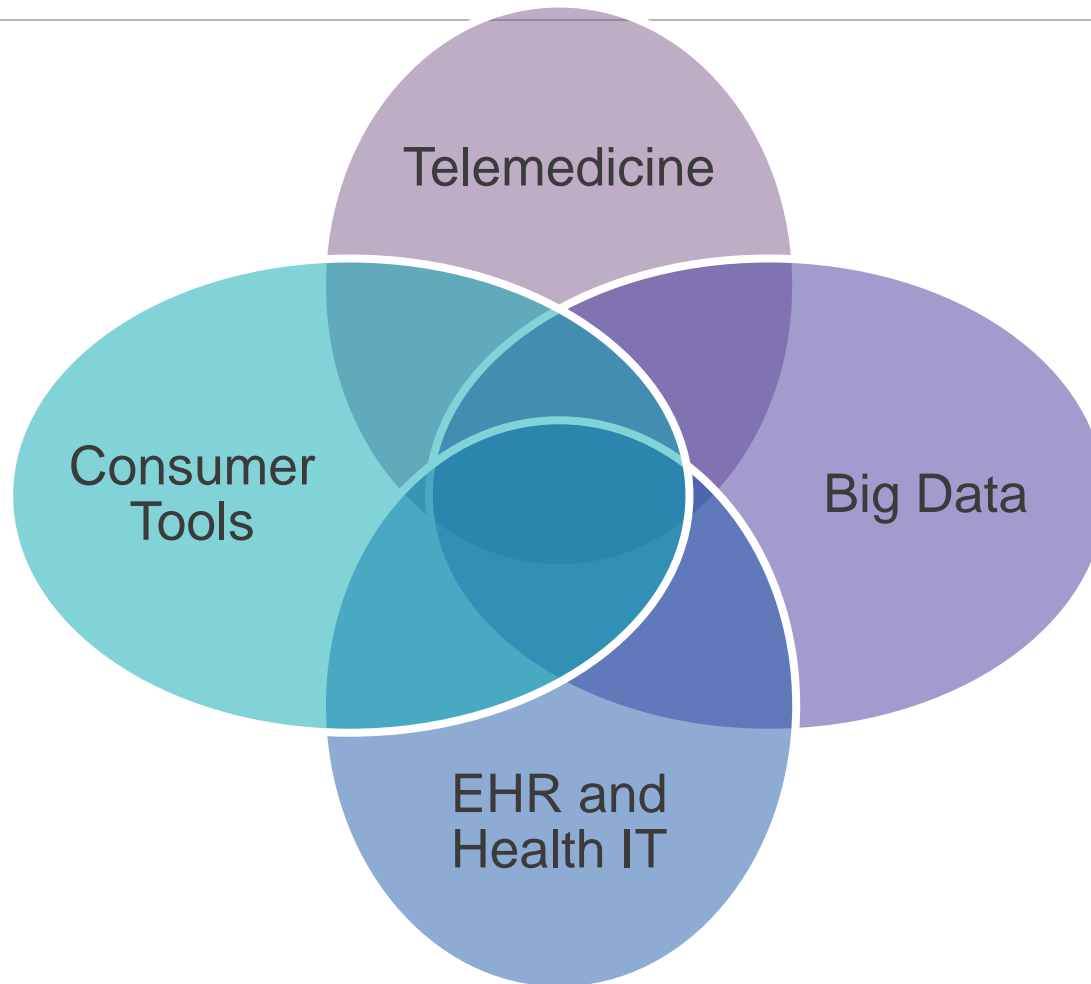
- Introduction
 - Defining Digital Health
 - Global Perspective on Potential Value Proposition
- Telemedicine Reimbursement
- New Payment Models – Value Opportunities
- State Issues
- Digital Health Technology Development and Deployment



Introduction



Introduction: *Defining Digital Health*



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:

<http://www.americantelemed.org/docs/practice-telemedicine/glossaryofterms.pdf>



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



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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”



You Are Here



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

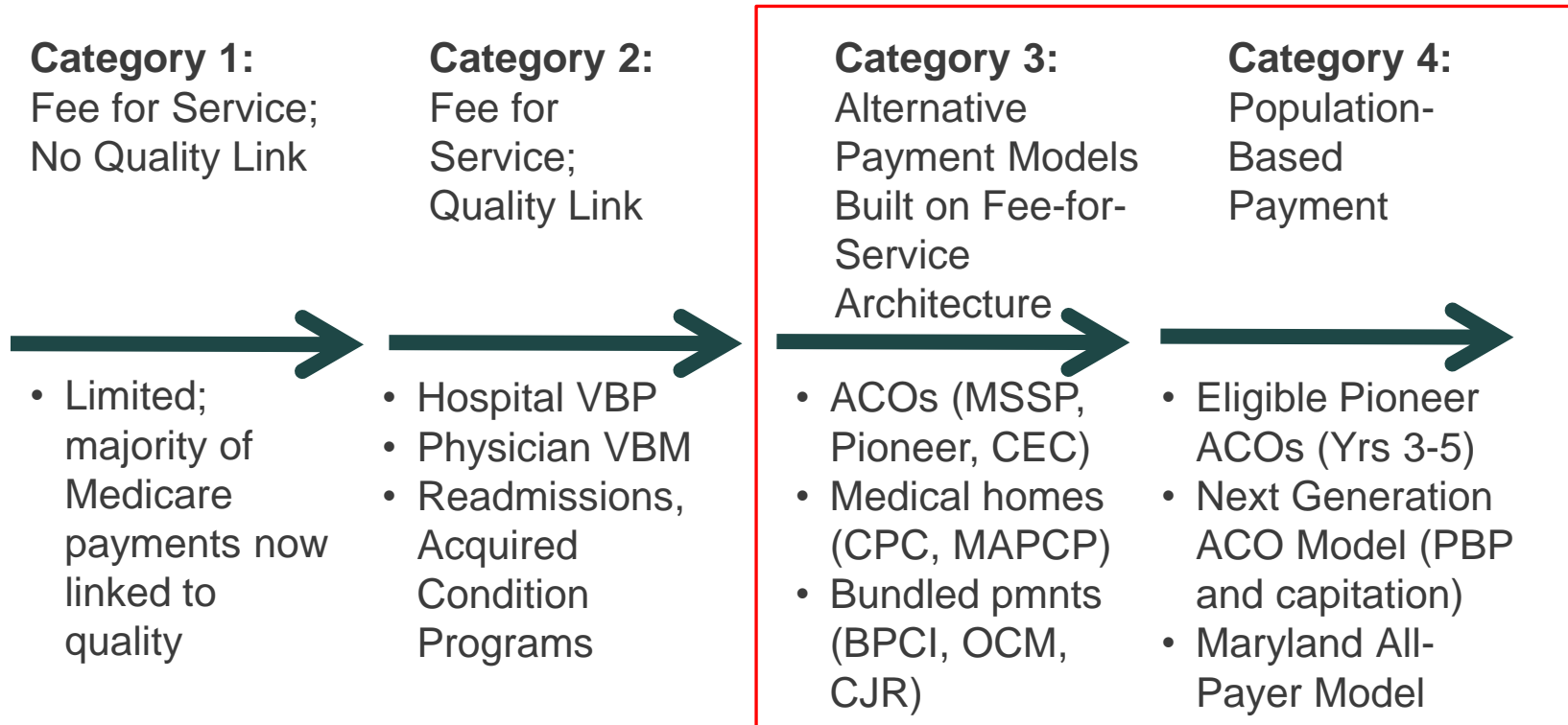
Increasingly demanding risk sharing, higher quality and greater efficiency

New Payment Models



Introduction: *Digital Health's Potential Value Proposition – Demand for Change*

Example: CMS Taxonomy of Payment Reform

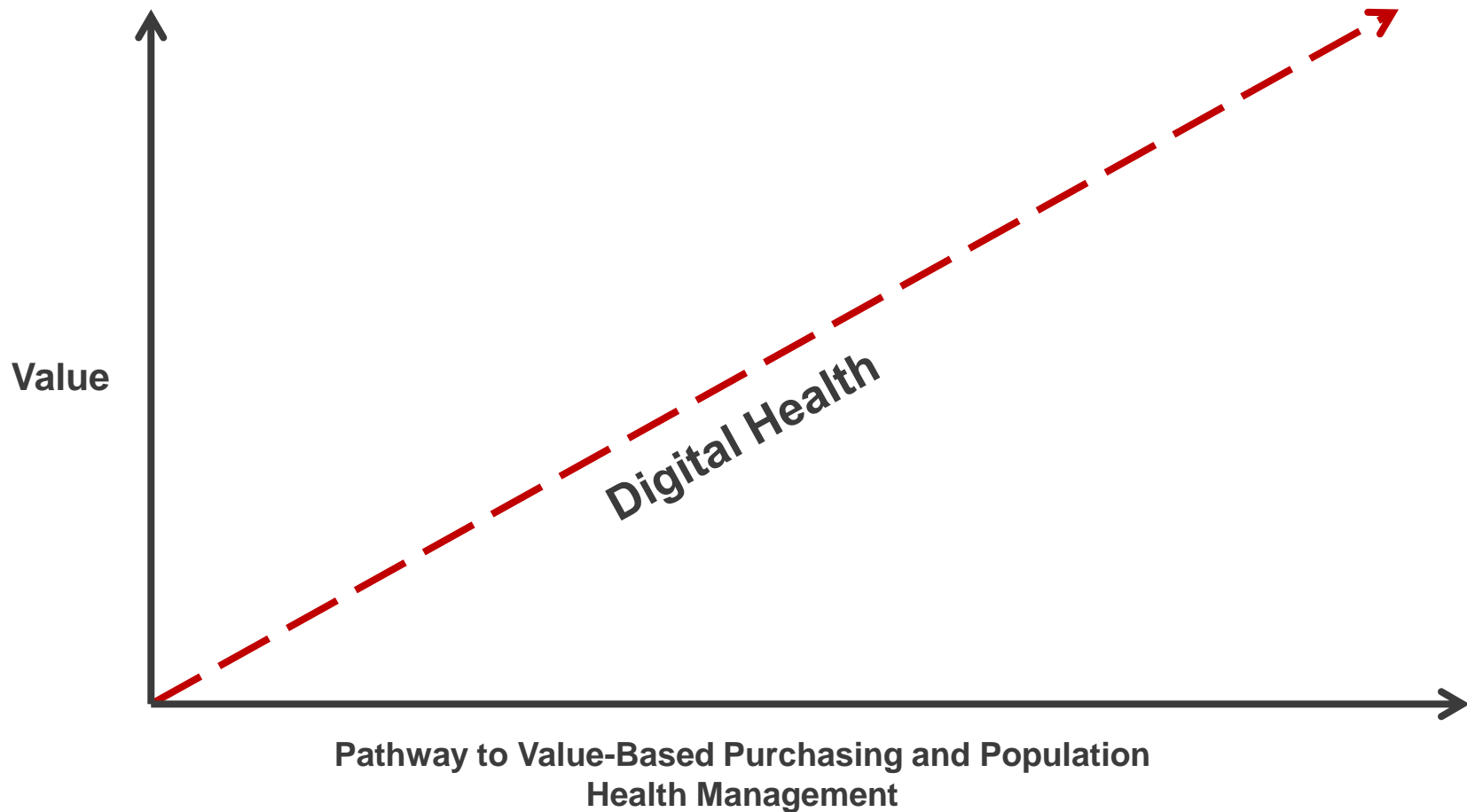


By 2016: 85% FFS payments tied to quality and value | **2018:** 90%

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*

Access

- Reduces ER visits
- Access to needed specialists
- Access for isolated patient populations

Quality

- Needed specialties at the right time
- Greater connectivity between patients and provider
- Better manage chronic conditions

Digital Health

Cost

- Can be lower cost option
- Long-term value (chronic conditions)
- More and better information to drive diagnosis and treatment decisions

Service

- Better communication between provider and patient
- Consumer empowerment and control
- Care when and where wanted



Telemedicine Reimbursement



Reimbursement: *Expansion*



Medicare

- Traditional high barrier to reimbursement
- Slow but steady expansion

Medicaid

- Experimentation
- Scattered and inconsistent requirements for reimbursement

Commercial

- Initial resistance
- Steady expansion of acceptance

Self Pay

- Increased investment by consumers
- Direct to consumer and managed care experience creating acceptance
- Information technology tools increasing demand

Payment Reform

- Benefits of telemedicine and other digital health tools being proven
- Direct reimbursement may be elusive, but economic value exists



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

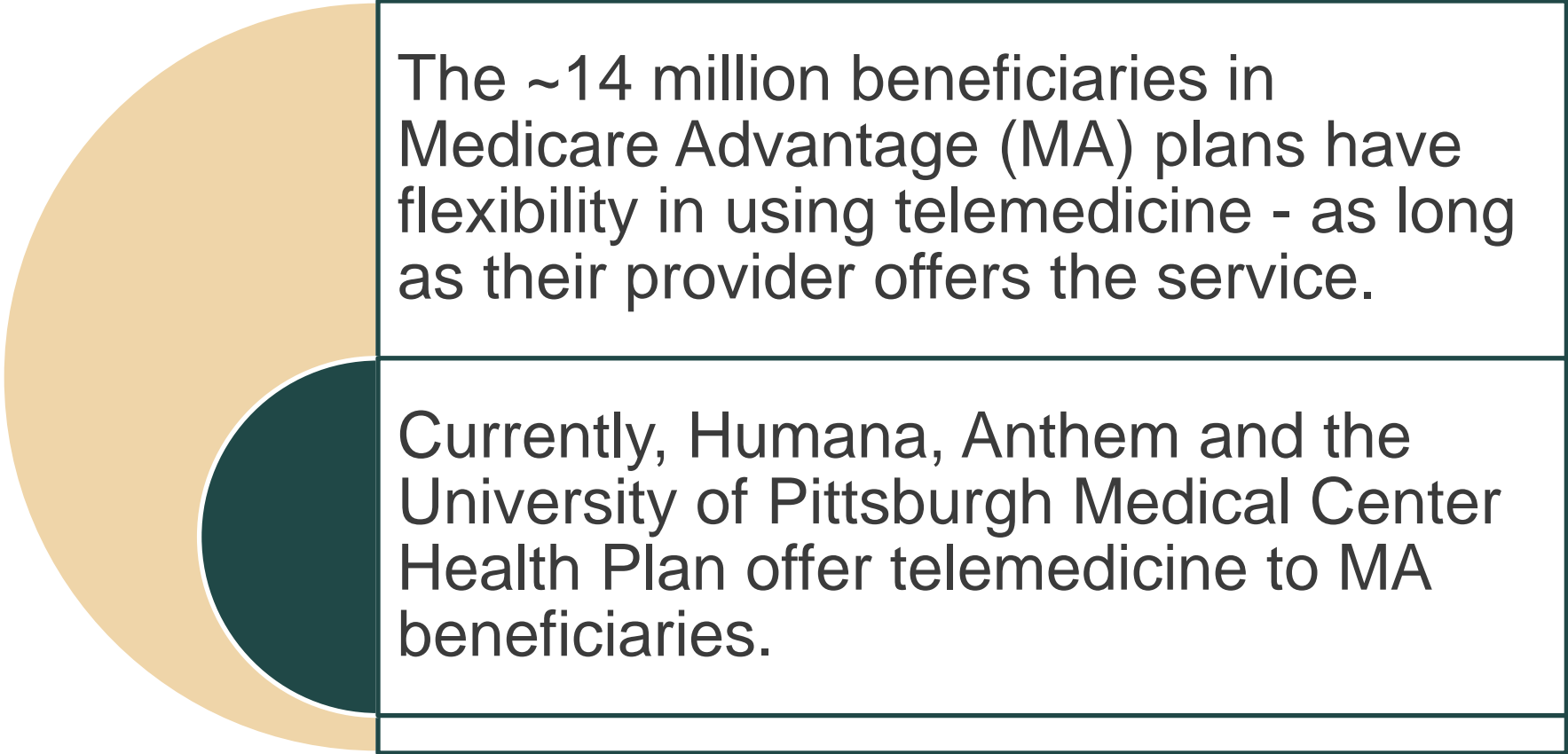
Reimbursement to the health professional = same as the current fee schedule.

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"



Reimbursement: *Medicare Advantage*

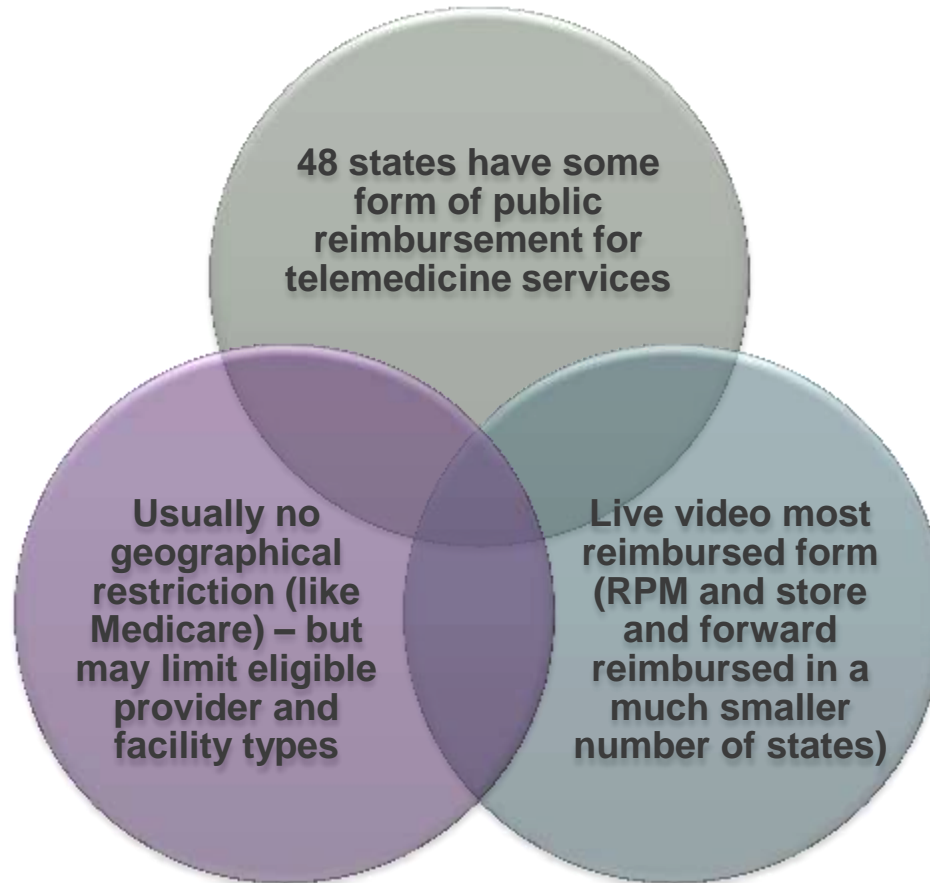


The ~14 million beneficiaries in Medicare Advantage (MA) plans have flexibility in using telemedicine - as long as their provider offers the service.

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



Reimbursement: *Medicaid*



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



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.).



Reimbursement: *Commercial Payers*

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



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

MACRA fundamentally changes Medicare physician payment

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



New Payment Models: MACRA – Examples of Digital Health Value Proposition

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

Key Provisions

Removes certain geographic and payment restrictions for telemedicine (and RPM) services provided to Medicare beneficiaries.

Creates a “bridge” telemedicine demonstration project (expanding providers’ use of telehealth in anticipation of MACRA).

Provides payments to APMs for RPM services and expands use of RPM for certain patients with chronic conditions and recent hospitalizations.

Proposed positive changes to MA plans designed to increase telehealth use.

Potential Impact

Expected to lower federal spending by \$1.8 billion over a 10-year timeframe.

Expected to improve patient access to services.



New Payment Models: *Maryland All-Payer Model – General Incentives*

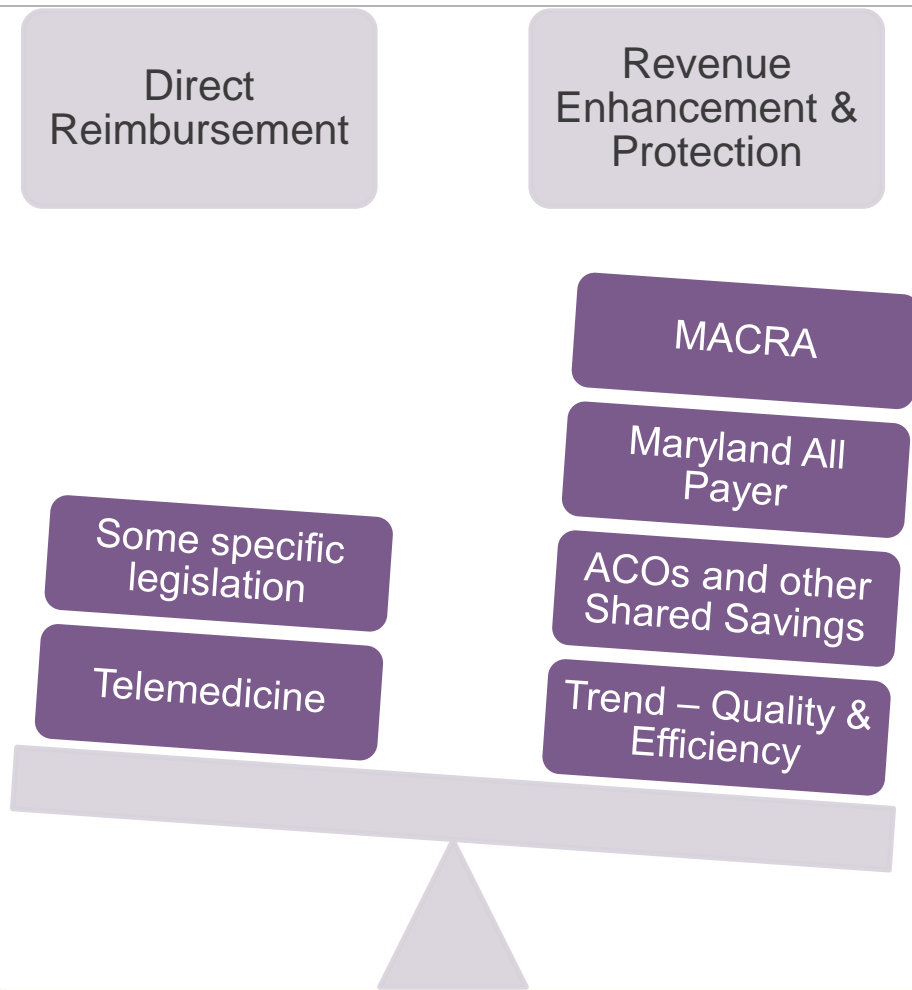
Hospitals operate under annual, global budget for all inpatient services for all payers.

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*



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



Digital Health Market: *Growth Projections*

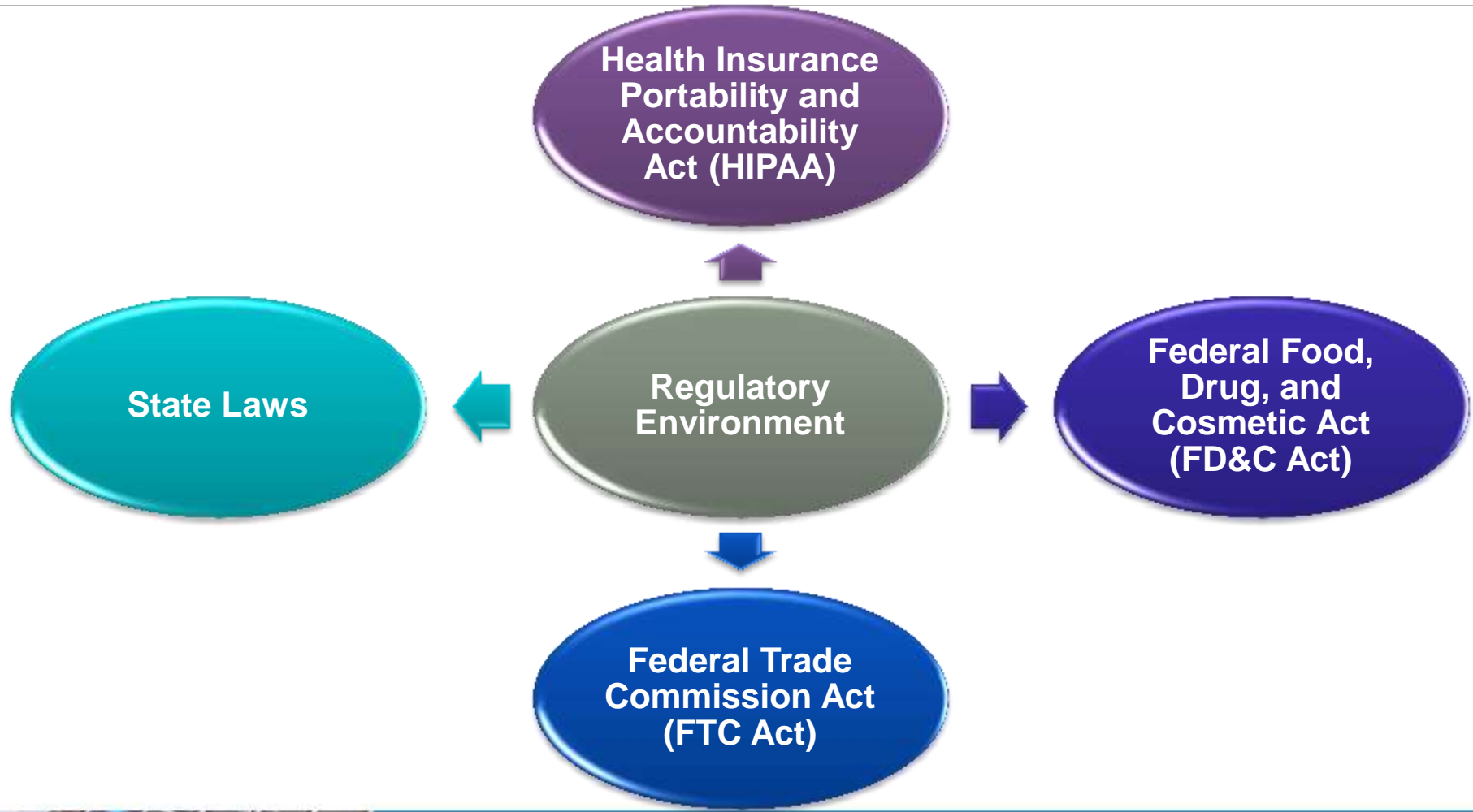
- Globally, the digital health market is predicted to grow to **\$34 billion** in 2020. (Mordor Intelligence, 2015).
- Domestically, annual investment in “on-demand” health services will quadruple from \$250 million to **\$1 billion** by 2017. (Accenture, 2015).
- The global internet of things (IoT) 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*



Digital Health Technology Development: *Regulatory Considerations*



Digital Health Technology Development: *Mobile Health Apps Interactive Tool*

The screenshot shows the Federal Trade Commission (FTC) website's 'Mobile Health Apps Interactive Tool' page. The header includes the FTC logo, the text 'FEDERAL TRADE COMMISSION PROTECTING AMERICA'S CONSUMERS', and a search bar. A navigation menu contains links for 'ABOUT THE FTC', 'NEWS & EVENTS', 'ENFORCEMENT', 'POLICY', 'TIPS & ADVICE', and 'I WOULD LIKE TO...'. The main content area features a blue banner with the text 'Developing a mobile health app? Find out which federal laws you need to follow.' Below the banner, it states the tool was produced in cooperation with the U.S. Department of Health & Human Services (HHS), the Office of the National Coordinator for Health Information Technology (ONC), the Office for Civil Rights (OCR), and the Food and Drug Administration (FDA). Logos for ONC, OCR, and FDA are displayed. A 'TAGS' section lists categories like Advertising and Marketing, Health Claims, Privacy and Security, Consumer Privacy, Data Security, Tech, and Health Care. A light blue box contains the text: 'You're developing a health app for mobile devices and you want to know which federal laws apply. Check out this interactive tool.' At the bottom, a list of links includes 'What Are the Laws?', 'Which Laws Apply to My Mobile Health App?', and 'Glossary'.

<https://www.ftc.gov/tips-advice/business-center/guidance/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.

4. Are you developing this app on behalf of a HIPAA covered entity (such as a hospital, doctor's office, health insurer, or health plan's wellness program)?

▼ YES

You likely are a HIPAA business associate, subject to the HIPAA Security Rule and specific provisions of the HIPAA Privacy and Breach Notification Rules.

GO TO QUESTION 5 to see if the FD&C Act also applies.

The HIPAA Privacy Rule

The HIPAA Privacy Rule requires appropriate safeguards to protect the privacy of identifiable health information (called protected health information or PHI when maintained or transmitted by a HIPAA covered entity or business associate), and sets limits and conditions on the uses and disclosures that may be made of such information without consumer authorization. The Rule also gives consumers rights over their health information, including rights to examine and obtain a copy of their health records, as well as to direct the covered entity to transmit their health information directly to a person or entity of their choosing, such as a mobile health app. Business associates are only required to comply with certain provisions.

The HIPAA Security Rule

The HIPAA Security Rule specifies a series of administrative, physical, and technical safeguards for covered entities and their business associates to use to assure the confidentiality, integrity, and availability of electronic PHI. Business associates must comply with the entire Security Rule.

The HIPAA Breach Notification Rule

The HIPAA Breach Notification Rule requires covered entities to provide notification to consumers, the Secretary of HHS, and, in some cases, the media following a breach of unsecured PHI. Business associates must provide notice to the HIPAA covered entity.

For additional guidance on whether HIPAA applies to your mobile app, see OCR's health app developer portal.

<https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool>



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

Patents

- Device specifications
- Methods of manufacture
- Software processes

Copyright

- Software code (object and source code)
- Compilations of data
- Look and feel

Trade secrets

- Software code (object and source code)
- Software algorithms
- Manufacturing processes
- Back-end technology

Trademark rights

- Product name
- Taglines



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.



Digital Health Technology Development: *App Terms of Service*

- 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



Digital Health Technology Development: *App Terms of Service - Legal Liability Issues*

- 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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