PROGRAM MATERIALS
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Introduction to Telehealth: Navigating State Compliance and Tracking Developments

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Introduction to telehealth: navigating state compliance and tracking developments

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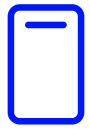
Agenda

- Defining digital health and telehealth
- Overview of the reimbursement landscape and current challenges
- Regulatory overview and enforcement
  - State
  - Federal
  - Professional boards
- Tracking developments

Defining digital health and telehealth

What is digital health?



Mobile health

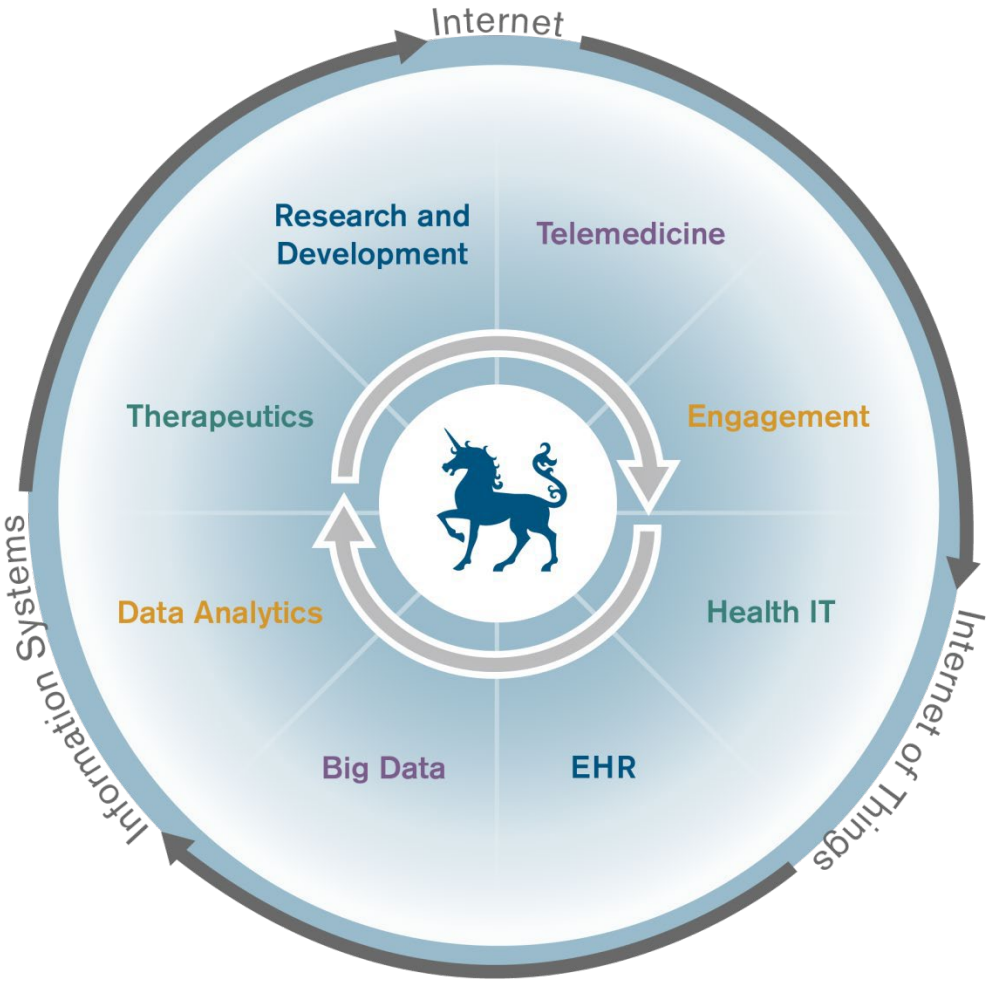
Health information technology

Wearable devices

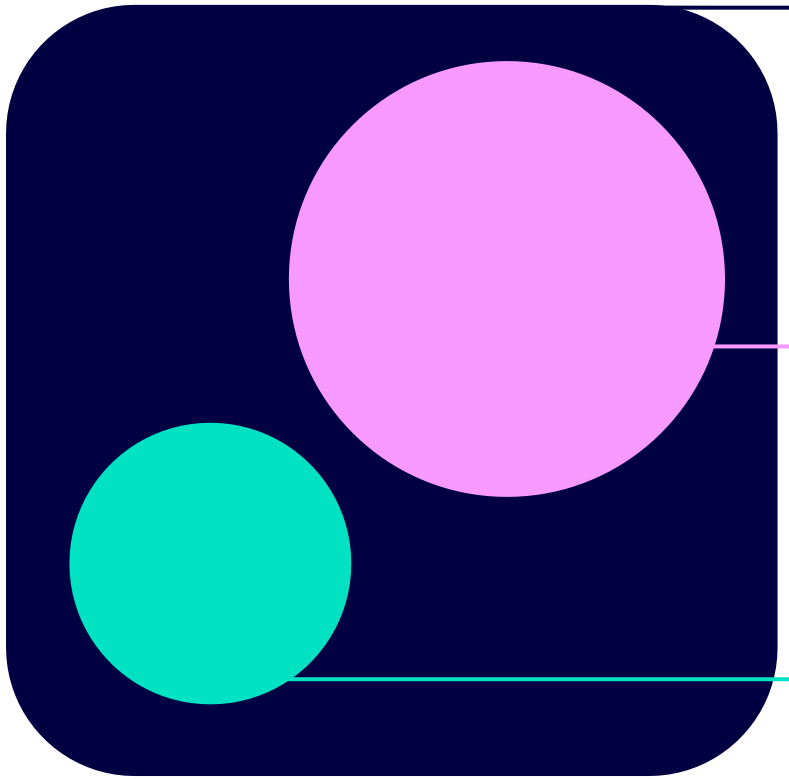
Telehealth and medicine

Personalized medicine

The digital health ecosystem



Defining telehealth



State and Accrediting Body Definition of Telehealth and Virtual Care Services

Health Plan Definition of Telehealth Services

Health Plan Definition of Virtual Care Services

Types of virtual care services

Remote Physiological Monitoring (RPM)

- RPM involves the collection and analysis of patient physiologic data that are used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition

Communication Technology-Based Services (CTBS)

- **Virtual check-in services:** brief check-in services furnished using communication technology that are used to evaluate whether an office visit or other service is warranted

- **E-visits:** A communication between a patient and their provider through an online patient portal (sometimes called a digital front door)

Drivers of digital health innovation

Providers

Patient engagement
Patient loyalty
Quality improvement
Population heath management demands
Building the brand
Capitalizing on "big data" interest and initiatives
Clinical decision support
Personalized medicine
Rapid real time learning

Leaders in innovation – old and new players

Those attracted to the "massive" health care market, including:

- pharma/biotech/medical device companies
- mobile app developers
- cloud services vendors
- informatics and analytics companies, and rapid learning vendors
- software and hardware entrepreneurs
- other consumer facing and provider facing technology developers

Consumers

"Next great thing"
Wearables
Real time data entry and access
Real time engagement with physician between visits
Ease of use
Quality of care

Payors

Lower cost
Consumer demand
Care management
Population health management demands
Real time quality metrics & metrics to support payment innovation

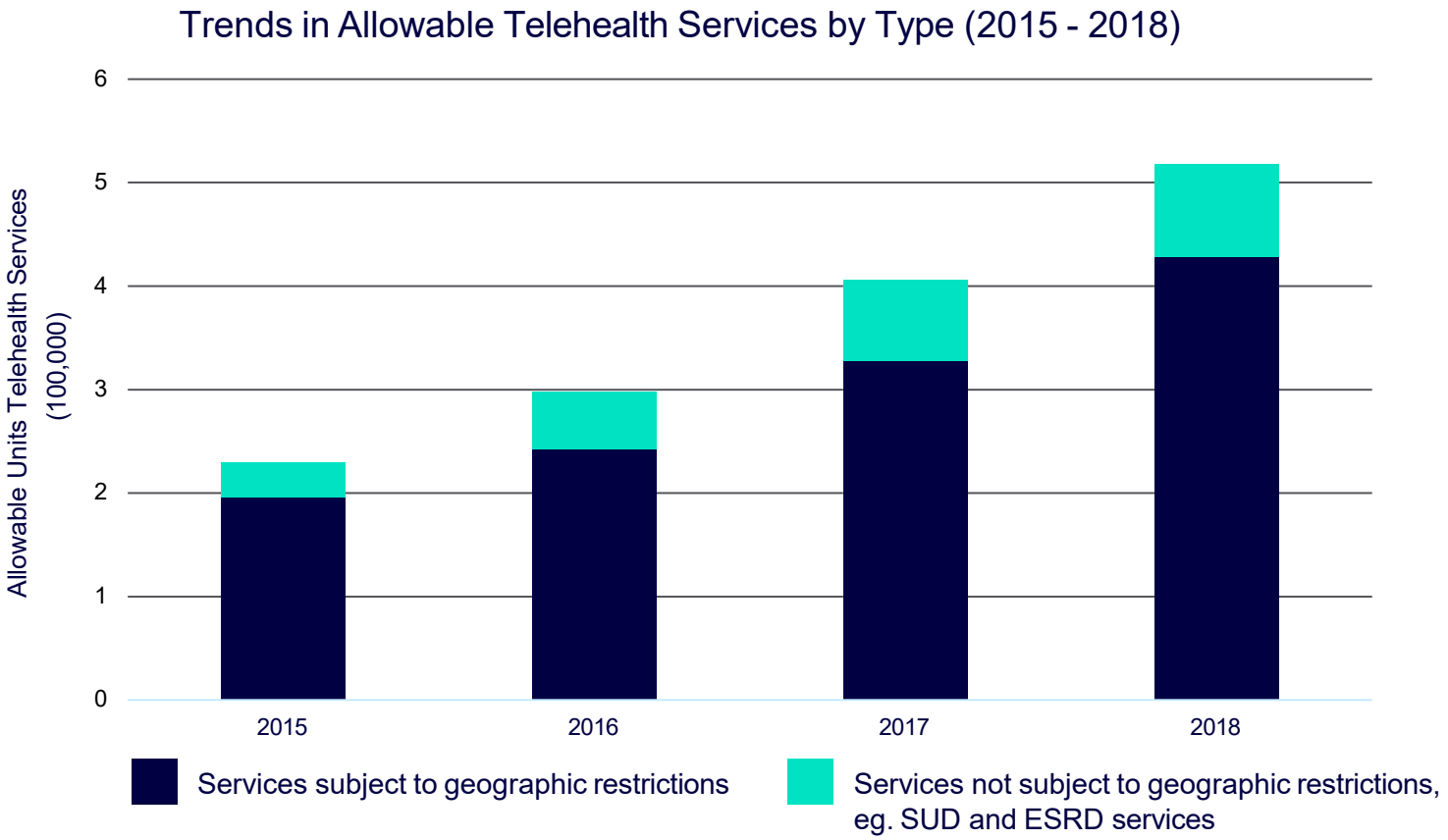
Government

Improved outcomes, quality and patient experience
EHR
Meaningful Use standards
Patient engagement technology
Expanding/improving current reimbursement models
Population health management strategies
Reduction of waste
Value-based purchasing

Stakeholders are exploring and implementing collaborations involving digital health for the innovation that is essential to each one's survival and success.

Telehealth and virtual care reimbursement

Telehealth utilization trends pre-pandemic



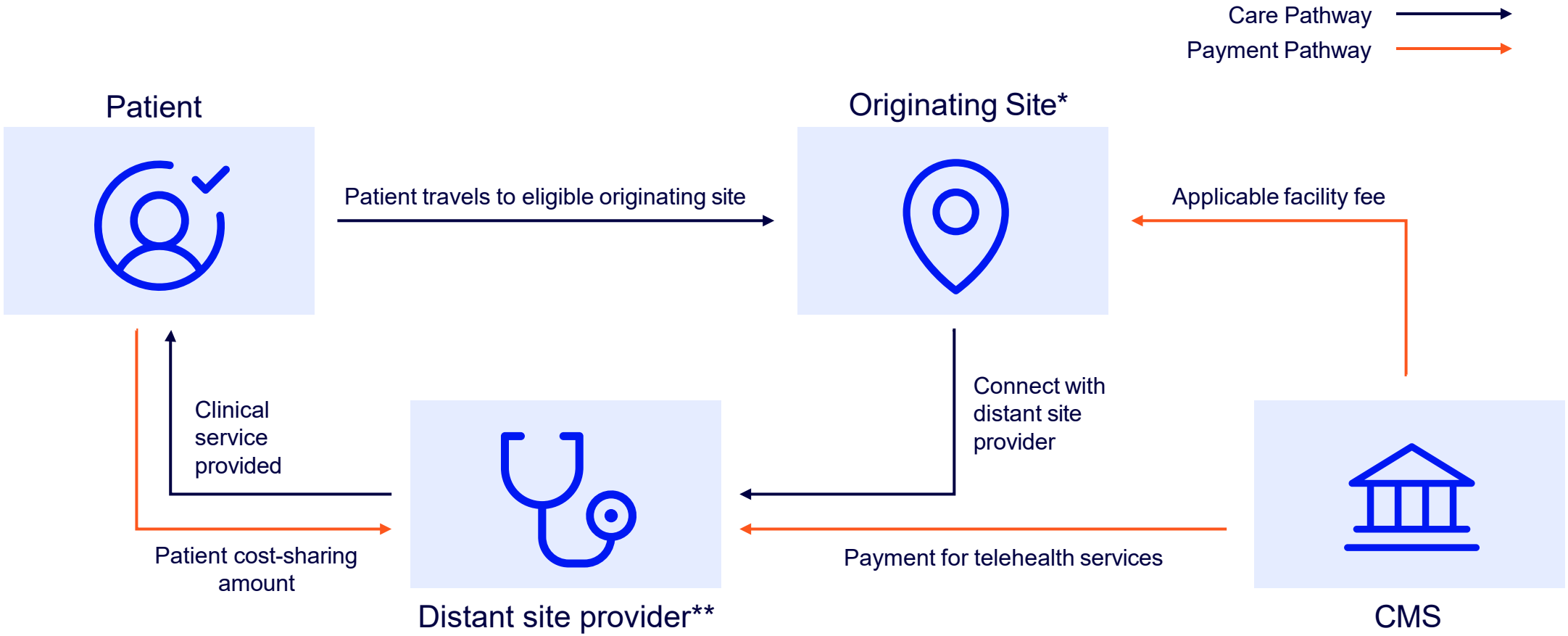
Between 2015 and 2018 telehealth utilization more than doubled in volume

Services not subject to geographic restrictions contributed to the increase is telehealth services

While the COVID-19 pandemic further increased telehealth utilization, continued incorporation of technology into healthcare delivery has been a trend across the nation for years

Source: Medicare Physician/Supplier procedure Summary (PSPS) Limited Data Set. Medicare Part B fee-for-service claims; Prepared by Partnership for Advancement of Virtual Care, a coalition of McDermott Plus Consulting

Delivery of Medicare telehealth services pre-pandemic



*Originating site providers can bill a standard facility fee, however no facility fee is paid if the originating site is the patient's home

**Distant site providers are reimbursed for telehealth services equal to the amount had the service been furnished in-person at the facility rate

Illustration of significant changes to reimbursement landscape: Medicare

	Pre-pandemic	Pandemic	Post-pandemic
Originating Site – Geography	Beneficiaries receiving telehealth services must be located outside a metropolitan statistical areas (MSAs) or in a rural area that is designated as a Primary Care or Mental Health geographic Health Professional Shortage Area (HPSA)	Originating site geographic requirements are waived; patients can be anywhere in the US	**Requires Congressional action** to modify originating site geographic requirements beyond September 30, 2025.
Originating Site – Facility Type	Beneficiaries receiving telehealth services must be located in certain clinical settings or facility types statutorily designated as eligible originating sites (A complete list of facility types is included in the Appendix)	Beneficiaries may receive telehealth services anywhere, including in their home	**Requires Congressional action** to establish the patient's home as an eligible originating site beyond September 30, 2025.
Provider Type	Type of providers eligible to furnish telehealth services to patients is limited (A complete list of provider types is included in the Appendix)	Types of professionals are expanded to include: • Physical therapists • Occupational therapists • Speech language pathologists	**Requires Congressional action** to expand types of providers eligible to furnish telehealth services beyond September 30, 2025.

* Current limit Section 4113(a) of the 2023 CAA
** Current limit Section 4113(b) of the 2023 CAA

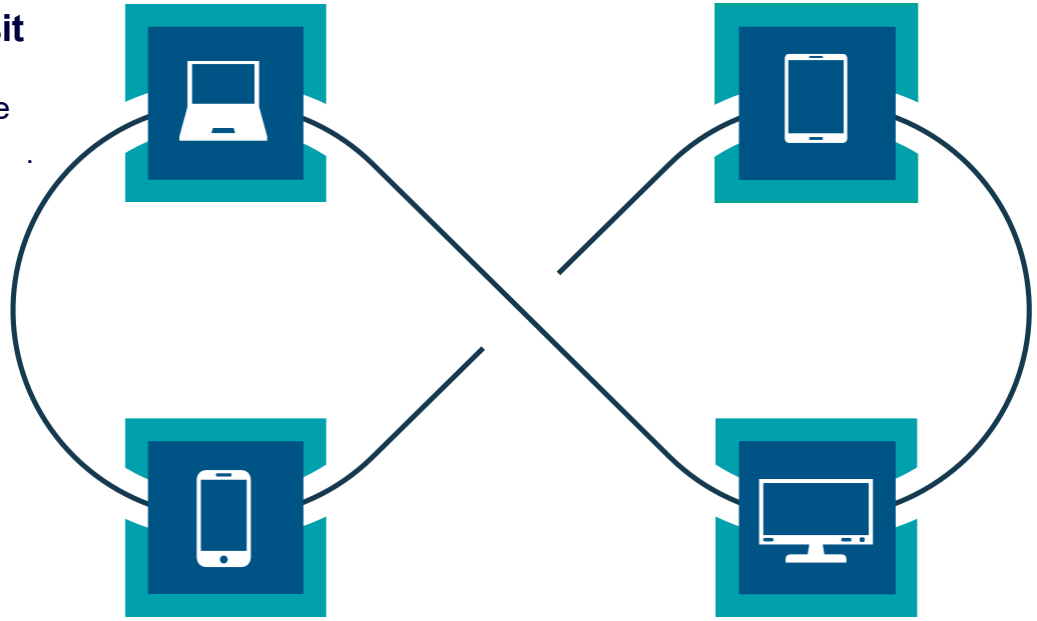
Mayo clinic study: health economic analysis of telemedicine visits

Study Design: Mayo Clinic introduced a postoperative video telemedicine follow-up program to understand the potential cost savings to patients at home, compared to face-to-face follow up in a standard clinic setting

Outcomes: The primary study outcome was potential savings to patients, secondary outcomes that were measured included avoiding travel and patient satisfaction. Cost savings to patients was categorized into 4 types: (1) travel costs, (2) lodging costs, (3) lost wages, and (4) meals and incidentals.

Average Savings per Telehealth Visit
Patients who utilized telemedicine were estimated to save $888 per visit on average

Savings for Non-Traveling Telehealth Patients
Patients who didn't need travel accommodations still saved an estimated $256 per visit



Increased Savings for Patients Traveling Long-Distance
Patients residing more than 1,635 miles round trip from a clinic saved an estimated $1,501 per visit

Patient Satisfaction for Telehealth Remains High
Patient satisfaction surveys indicated that patients who strongly agreed and agreed with satisfaction with their telemedicine postoperative follow-up visit was 94% to 98%

Source: Demaerschalk, B., et.al. (2020). Health Economic Analysis of Postoperative Video Telemedicine Visits to Patients' Homes. Mayo Clinic. https://doi.org/10.1089/tmj.2020.0257

Continued challenges for virtual care providers

Uncertainty regarding continued telehealth flexibilities at the federal level

Continued ambiguity in state law, particularly for telehealth companies that are using innovative care delivery models

Navigating varying payor requirements (e.g., covered modalities and service offerings)

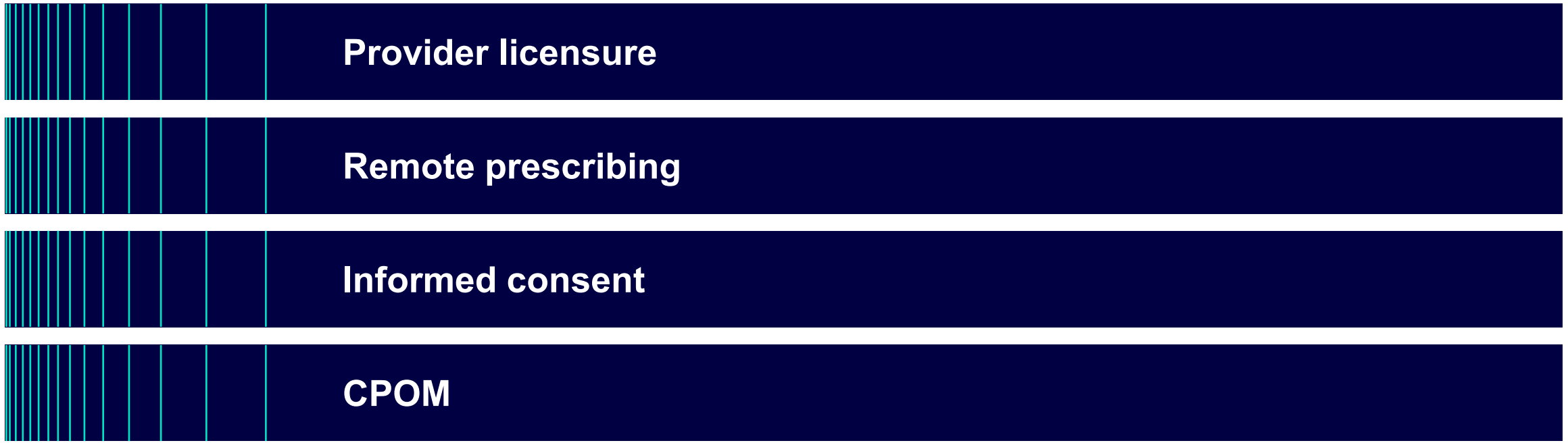
Risk analyses / enforcement

Laws and regulations

Legal and regulatory considerations

Technology Contracting and Development	**Privacy and Security**	**IP/Data Strategies**	**Care Delivery Considerations**	**FDA/Regulatory**
Reimbursement / Payment Strategy	**Market Strategy**	**Investment & M&A**	**Licensing and Collaborations**	**Federal and State Guidance**
Fraud and Abuse	**Scope of Practice and Standard of Care**	**International Considerations**	**Corporate Practice Considerations**	**Prescribing Practices**

State-level: current landscape



State-level: potential future landscape

- Professional licensure exceptions
- Increased compact activity
- Eased remote prescribing rules
- Expanding Medicaid coverage and easing enrollment requirements

How is the federal government regulating telehealth?

- **FTC enforcement of wellness apps**
  - The FTC regularly brings enforcement actions under Section 5(a) of the FTC Act, which prohibits companies from engagement in “unfair or deceptive acts or practices in or affecting commerce.”
  - The FTC is currently focused on whether companies that operate “health apps” and “wellness apps” and has expressed its intent to continue monitoring the compliance of these apps with this law.

Notes on federal laws regulating telehealth

There are dozens of federal laws that also apply to telehealth programs, including laws that regulate controlled substance prescribing, privacy and security, and fraud and abuse

If government payors are involved, federal (in addition to state) fraud and abuse laws apply

The FDA has largely deregulated telehealth platforms that connect patients and healthcare providers or providers with other providers, but may indirectly regulate aspects of telehealth if used for FDA-regulated clinical research

DEA requirements for controlled substance prescribing via telehealth (current flexibilities extended through December 31, 2025).

Design and follow thoughtful risk mitigation strategies

Implement safeguard for marketing and advertising

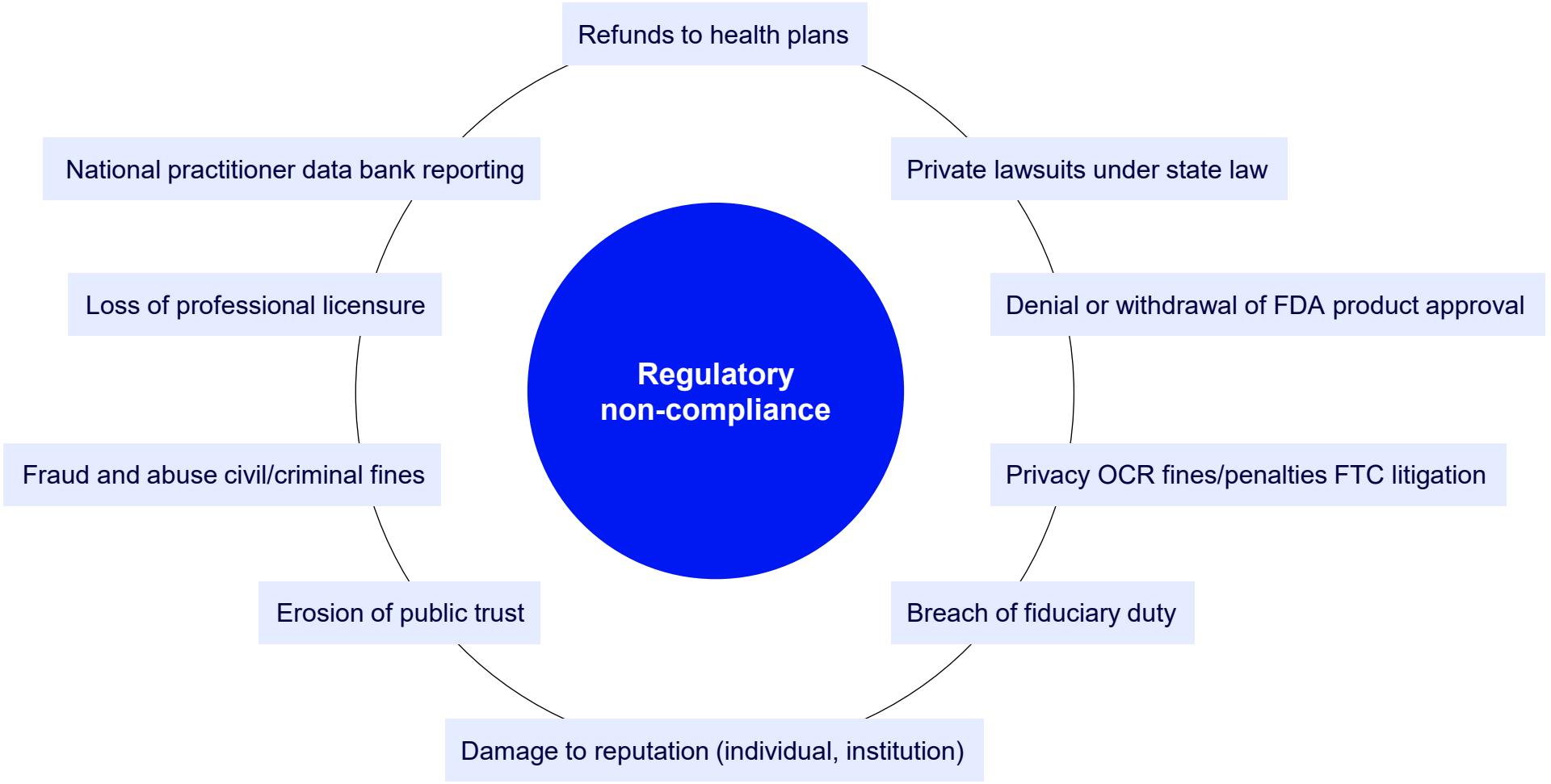
Establish the physician-patient relationship

Maintain a robust compliance program

Review billing and coding practices

Enforcement activity

Enforcement risks/implications



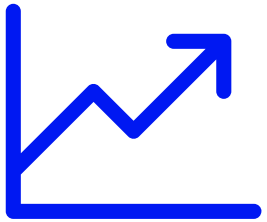
Scrutiny and enforcement trends

Telehealth is subject to even greater scrutiny than before

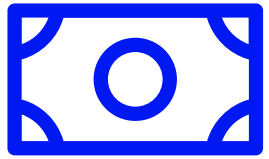
- Continued reliance on waivers and allowances that started during the pandemic
- DEA extensions related to controlled substance prescribing
- Rush of new entrants in the market
- Scrutiny about tax payer dollars
- Increased media attention

Scrutiny and enforcement trends (State-level)

Increase in state licensure investigations



Increase in Medicaid program audits



Increase in commercial payor audits

Tracking legislative and regulatory activity

Tracking tools and resources

- Center for Connected Health Policy (“CCHP”)
- LegiScan
- State-specific websites for regulations and professional boards
- Public blog materials, e.g., Of Digital Interest
- Google and other search engine “alerts”
- Affinity group membership and websites

Trends and examples

- Compact activity
  - Examples: Arkansas and Michigan
- Parity and Reimbursement
  - Senate Bill 372 and House Bill 869. Makes pandemic allowances related to audio-only coverage and telehealth payment parity permanent across payers.
- Practice Standards
  - House Bill 2435. Amends Minnesota Telehealth Act in the Insurance Code to extend the provision providing that “telehealth” includes communication between a health care provider and a patient that solely consists of audio-only communication to July 1, 2028 (was set to expire July 1, 2025).
  - Senate Bill 94 and House Bill 825. As applied to health care practitioners, the definition of telehealth is amended in this bill to include audio-only. Additionally, language in the bill would ensure providers are not limited in their choice of platform to use to deliver health care services.
- Access to Care
  - House Bill 701. Enables a health care provider to conduct a telehealth prescreening for terminally ill patients located in any state or jurisdiction who have exhausted FDA-approved options to access investigational drugs. Further, a patient may use remote signing to consent to treatment. This simplifies the consent process, encouraging more healthcare entities to participate in enhancing access for terminally ill patients to investigational treatments.
  - House Bill 3709. Beginning with the 2025-2026 school year, provides that each public institution of higher education with student health services shall provide enrolled students with access to health care professionals authorized under State law to prescribe contraception which may be provided through telehealth.

Licensure compact overview

Nurse Licensure Compact	Interstate Medical Licensure Compact (IMLC)	Audiology & Speech-Language Pathology Interstate Compact (ASLP-IC)	Occupational Therapy Licensure Compact (OT Compact)
Psychology Interjurisdictional Compact (PSYPACT)	Physical Therapy Compact	Advanced Practice Registered Nurse Compact (APRN Compact)	EMS Compact
Interstate Counseling Compact	Social Worker Licensure Compact	Dietitian Licensure Compact	Physician Assistant Compact (PA Compact)

Best practices

Monitor updates on a regular cadence

Set tracking alerts for high priority legislation

Create plan for notifying stakeholders of changes

Monitor implementation dates

Thank you

Appendix

Key Medicare terms – defining telehealth

Term	Definition
Telehealth	Medicare defines telehealth services by statute and allows the Secretary to add services on an annual basis using an established process.
Medicare Telehealth Service List	The Centers for Medicare and Medicaid Services (CMS) maintain a list of services payable under the Medicare Physician Fee Schedule when furnished via telehealth. CMS adds and removes services from the list via annual rulemaking.
Distant Site Practitioner	The distant site practitioner provides the telehealth service to the Medicare beneficiary and is reimbursed equal to the amount had the service been provided in-person. 42 U.S.C. 1395m(m)(2)(A)
Originating Site	Location of an eligible Medicare beneficiary at the time the service is furnished and only if that site is located in an area that is designated as a rural health professional shortage area, in a county that is not included in a Metropolitan Statistical Area; or from an entity that participates in a federal telemedicine demonstration that has been approved by the Secretary as of December 31, 2020. Originating sites may only be: physician or practitioner office; critical access hospital, rural health clinic, federally qualified health center, hospital, hospital-based or critical access hospital, skilled nursing facility, community mental health center, renal dialysis facility under certain circumstances, and the individual's home for substance use disorder services.
Distant Site	Site at which the physician or practitioner is delivering the service when the service is provided via a telecommunications system (42 U.S.C. 1395m(m)(4)(A);42 C.F.R. 410.78(a)(2))
Telehealth Originating Site Facility Fee	Originating site facility fee is statutorily set and updated annually by the medical economic index (MEI). For CY 2021, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge, or $27.02. No facility fee will be paid if the originating site is the patient's home. 42 U.S.C. 1395m(m)(2)(B)(ii)
MPFS Facility/Non-Facility Rates	The payment rate for professional services delivered in places of service that are designated as facility settings, such as telehealth, inpatient hospital, outpatient hospital. A complete list can be found in the Medicare Claims Processing Manual, Chapter 12.

Key Medicare terms – defining virtual care

Term	Definition
Remote Physiological Monitoring (RPM)	RPM involves the collection and analysis of patient physiologic data that are used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition. (85 Fed. Reg. at 84,542) RPM services are defined as virtual care services, not telehealth services.
Communication Technology-based Services (CTBS)	Short patient-initiated communications with a healthcare practitioner. Real-time audio-only telephone interactions in addition to synchronous, two-way audio interactions that are enhanced with video or other kinds of data transmission are appropriate modalities to furnish CTBS services. CTBS services are defined as virtual care services, not telehealth services.
E-Visits	Non-face-to-face patient-initiated communications through an online patient portal. E-visits are defined as virtual care services, not telehealth services.
Virtual Check-ins	Short patient-initiated communications with a healthcare practitioner. E-Visits are defined as virtual care services, not telehealth services.