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The Telehealth Space: Legal & Regulatory Issues
FocusOn Call

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Agenda

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2. Telehealth Data/Studies
3. Telehealth Applications
4. Legal/Regulatory Issues for Telehealth Providers
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5. Initiatives
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Introduction

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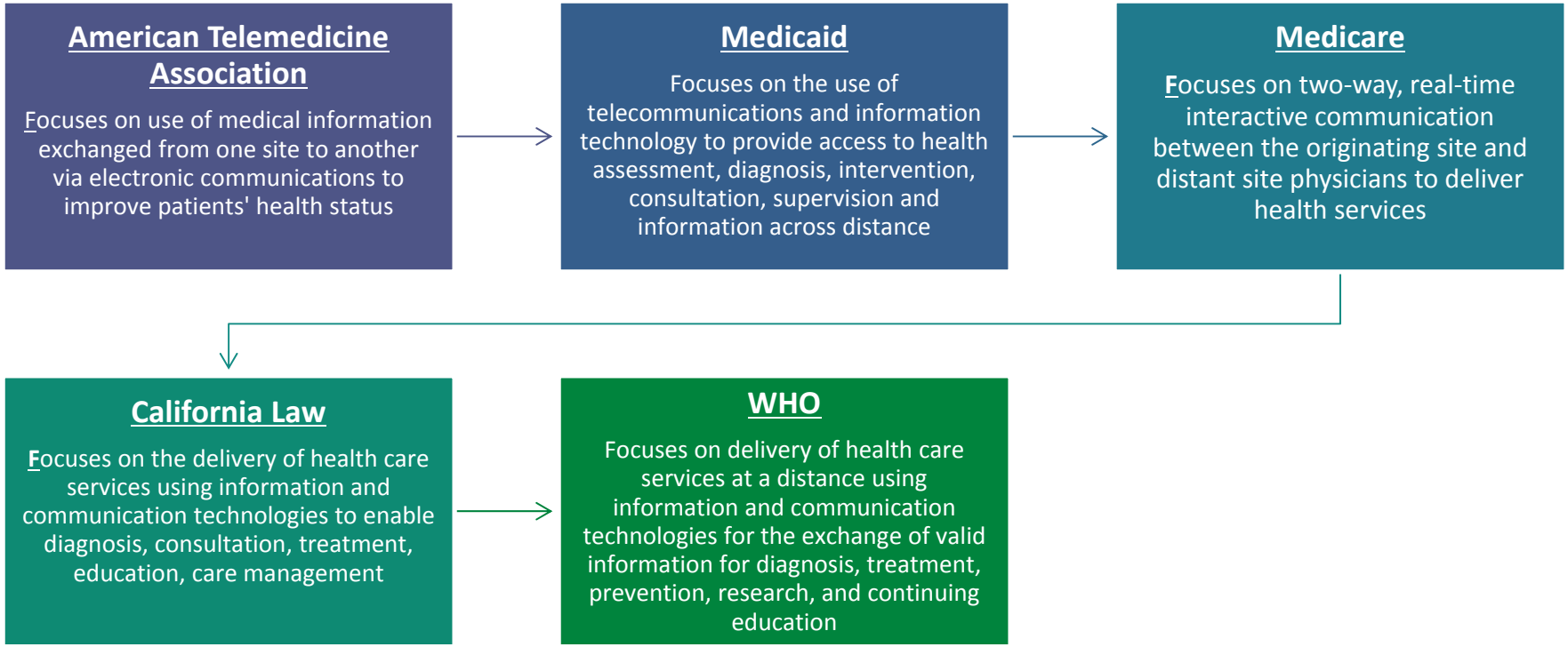
Definitions of Telehealth

"Telehealth" and "Telemedicine" Are Often Used Interchangeably



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Usage of Telehealth

- Patient care
- Remote patient monitoring
- Medical education of providers
- Consumer medical/health information

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Healthcare Landscape

- US health care landscape changing from fee-for-service to pay-for-performance (outcomes, quality)
- Increase in use of integrated delivery models such as ACOs, bundled payments, medical homes, readmissions reduction initiatives
- Consumer demand for in-home treatment
- Telehealth viewed as an efficient and cost-effective care delivery vehicle
- Available technology

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Employer Landscape

In 2018, the Cadillac Tax places a 40 percent non-deductible excise tax on plan expenditures that exceed certain thresholds

Employees in many cases are hesitant to take time off work and pay the co-payments associated with the doctor's visit, especially for minor ailments.

Employees may forego these visits, which can cause relatively minor health issues to escalate into costly conditions.

Some large employers have created on-site clinics where employees can receive routine sick care and preventive visits without taking time off work

High costs associated with creating on-site clinics

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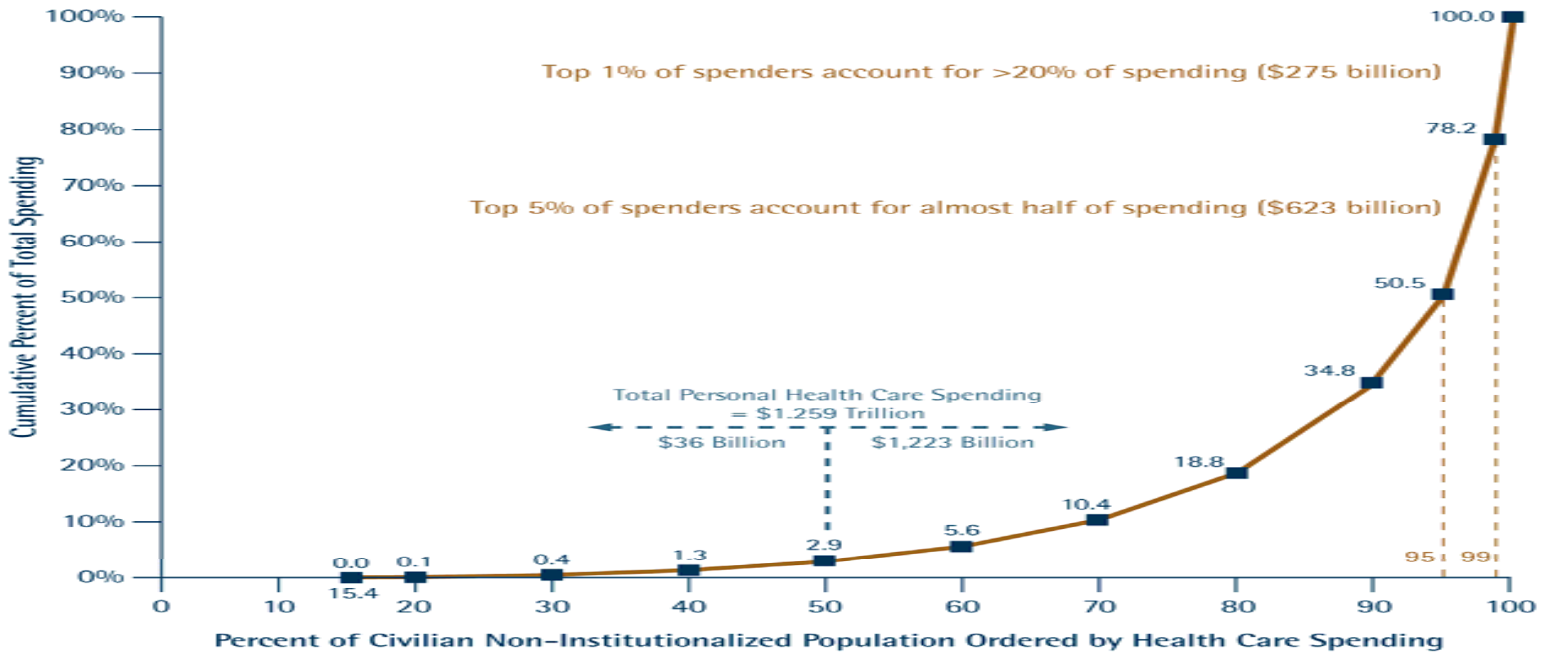
Health Care Spending

5% Of The Population Accounts For Almost Half of Health Care Spending and 20% Of The Population Accounts For About 80% Of The Spending.

FIGURE 1. CUMULATIVE DISTRIBUTION OF PERSONAL HEALTH CARE SPENDING, 2009



NIHCM Foundation analysis of data from the 2009 Medical Expenditure Panel Survey.

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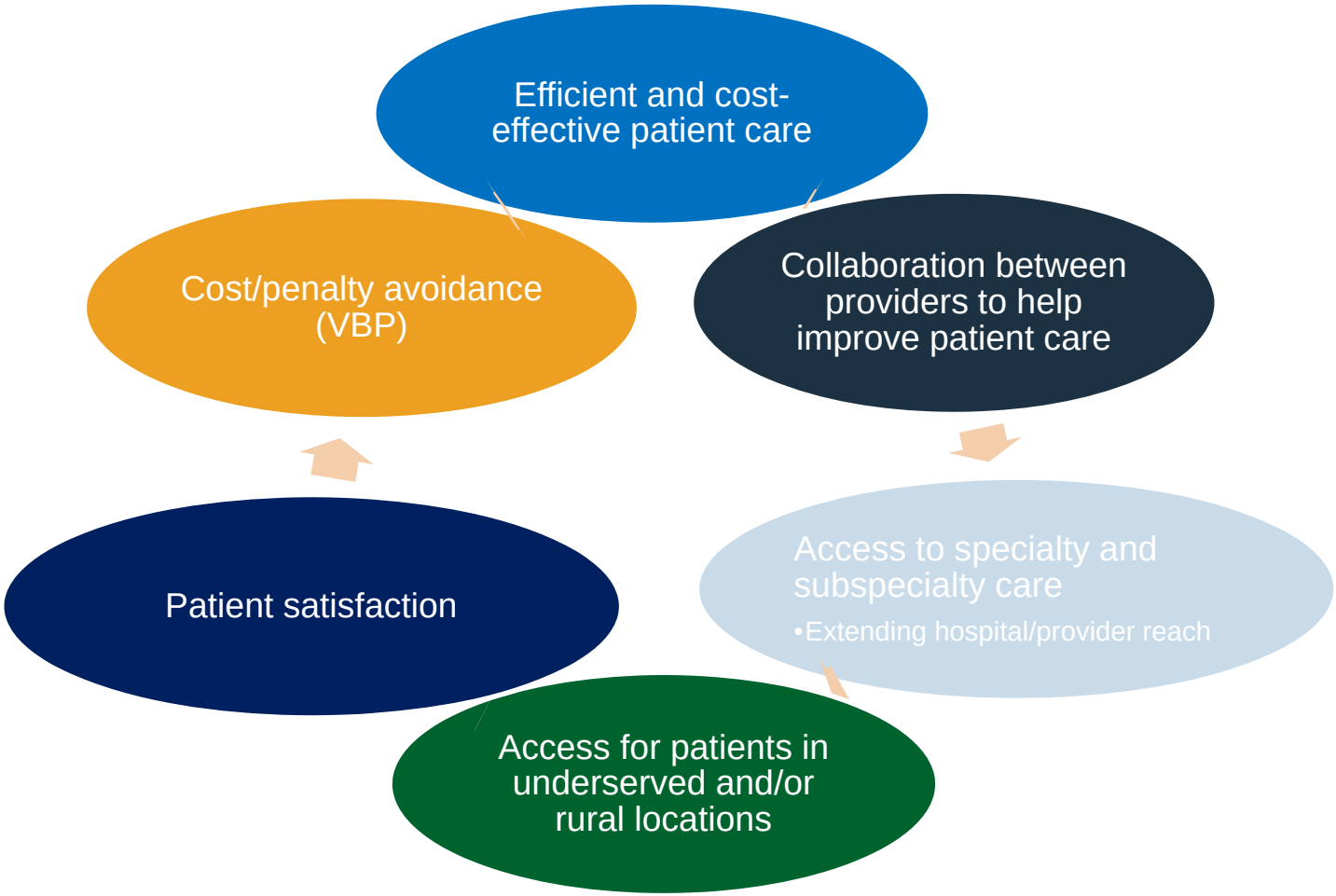
Benefits of Telehealth



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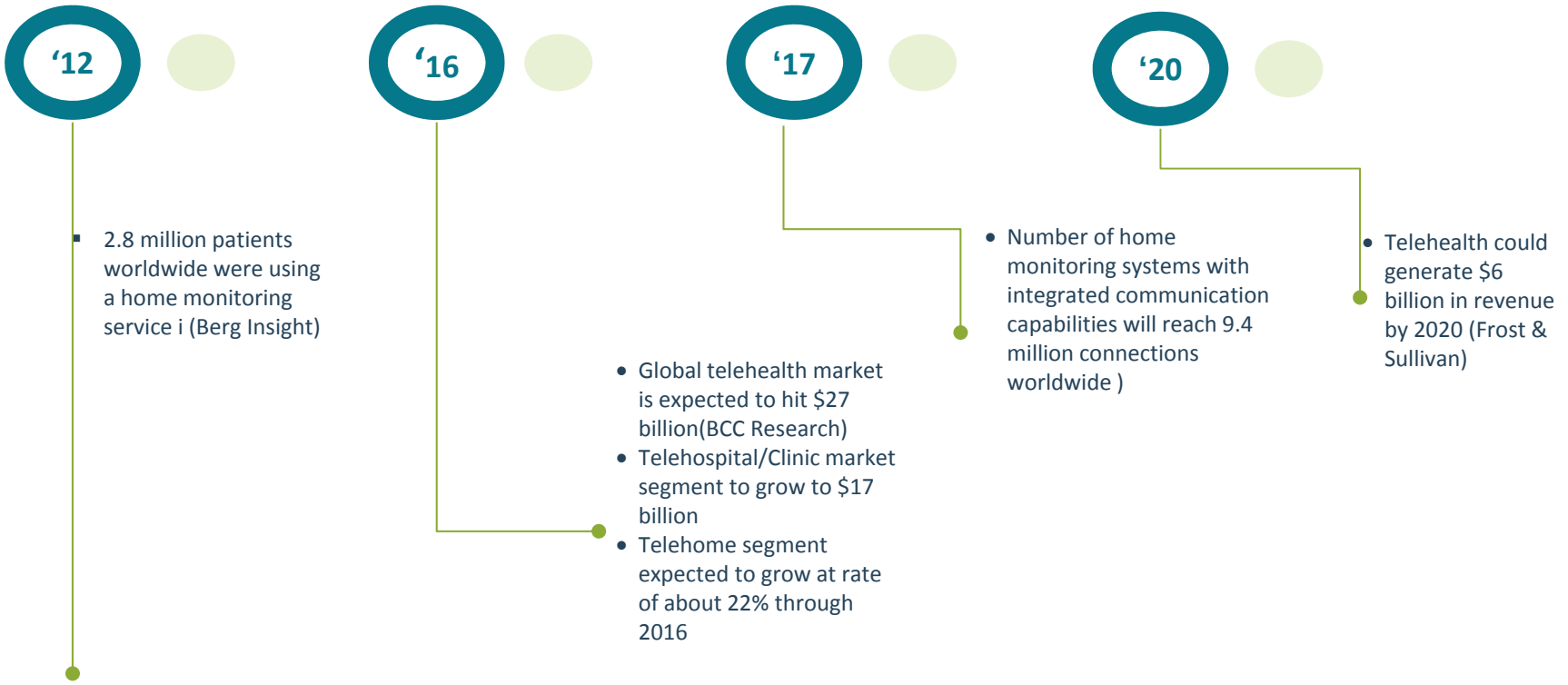
Telehealth Market Overview

"Hundreds of telehealth networks connecting over 2,000 health institutions"



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Employer Market

Per Towers Watson study, US employer could save up to $6 billion per year

- If all patients routinely engaged in remote consults for appropriate medical problems instead of visiting emergency rooms, urgent care centers, and physician offices
  - Only 22% of employers currently offer telehealth services for their employees
  - Most vendors see a per-member utilization rate of less than ten percent (expected to grow)
  - 37% companies surveyed by Towers Watson plan to offer telehealth by 2015
  - 34% considering doing so in the next three years

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Telehealth Drivers

- **Increasing Aging Population**
  - 365 million population by 2030
  - 65 and over 19% of population 2030
- **Fewer Physicians**
  - Shortfall of 63,000 physicians by 2015
  - Shortfall of 130,000 physicians by 2025
- **Payment for Value/Outcomes**
  - Driven by increased patient costs and post-acute care strategies designed to reduce readmissions
- **Ubiquity of Technology**
- **Use Outside US**

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Patient Trends

- Anthem: 74% of US consumers indicated that they would use telehealth services (and the number is expected to grow)
- Cisco: 76% of patients choosing access to care over human interaction with their care provider
  - 70% are comfortable communicating with doctors via text, email, video instead of seeing them in person
  - 30% of people use computers or mobile devices to check for medical or diagnostic information
  - 63% of customers are comfortable with storing their medical records on a cloud
- Telehealth & eHealth Journal study: 75% of respondents said they would not use telehealth unless it was covered by their insurance

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Telehealth Data/Studies

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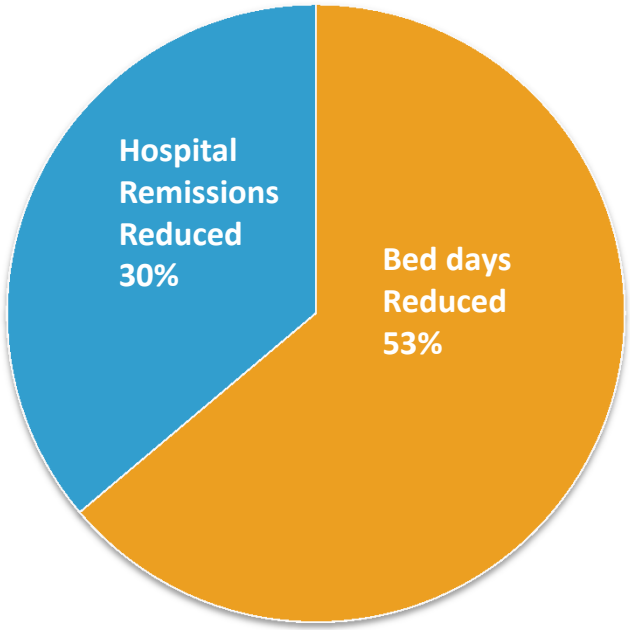
VA Telehealth Outcomes (2012)

VA Telehealth Recognized as an International Leader in Telehealth Development

Home Telehealth



- 1.4 million telehealth consultations
- 30% of patients in rural areas
- Telehealth services growing by 70% annually
- Telemental Health
  - 200,000 telemental health consultations to 75,000 patients
  - Home telehealth devices helped about 7,000 patients with chronic mental health conditions live independently in their homes

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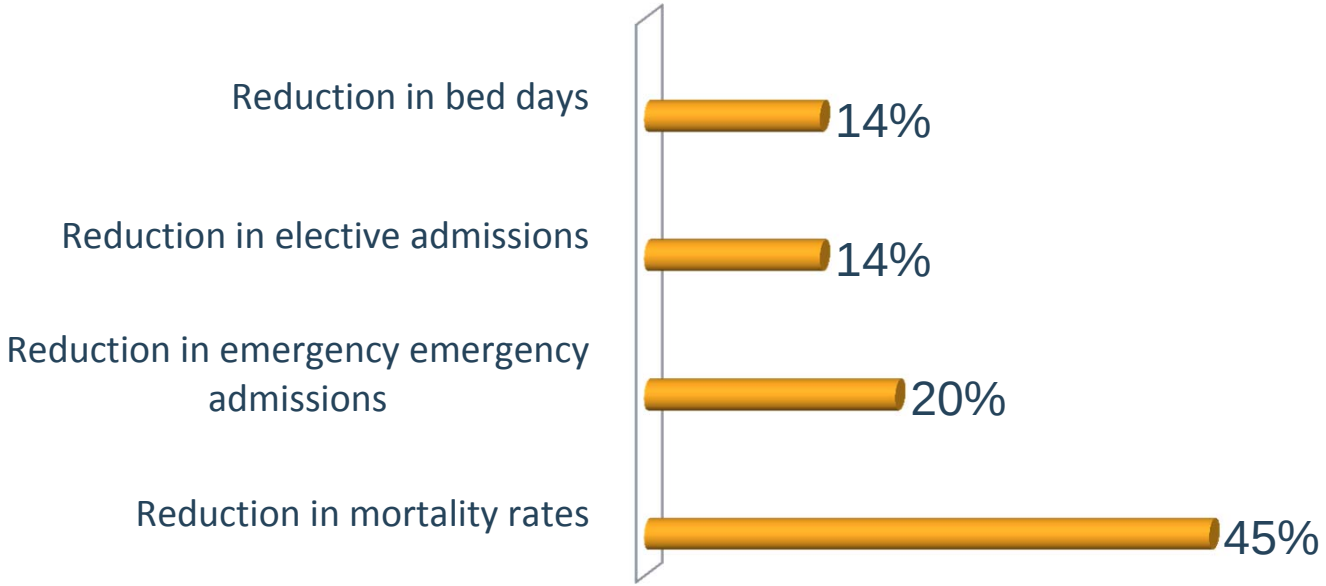
Largest Telehealth Study /

BRITISH MEDICAL JOURNAL 2012

UK Dep't of Health Whole System Demonstrator Program

6,191 Patients with Diabetes, COPD, Chronic Heart Failure

Randomized Controlled Trial



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Telehealth Applications

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Telehealth Systems

Telehealth Service	Description
Real Time	Provider and patient communicate live via videoconferencing. Uses include telebehavioral health, telehomecare, telecardiology. Remote consults (teleconsults) with specialists, PCPs, counselors, social workers, and other health care professionals.
Store & Forward	Digital images, video, audio, clinical data, etc. captured and stored on a patient's computer/mobile device and then transmitted securely to a provider for later study or analysis. Used often in teledermatology and telepathology.
Remote Monitoring	Patient uses a system that fees data/information from sensors and monitoring equipment to an external monitoring center so that doctors and/or healthcare professionals can monitor a patient remotely. Used to monitor chronic conditions such heart disease, COPD, or diabetes, or asthma.

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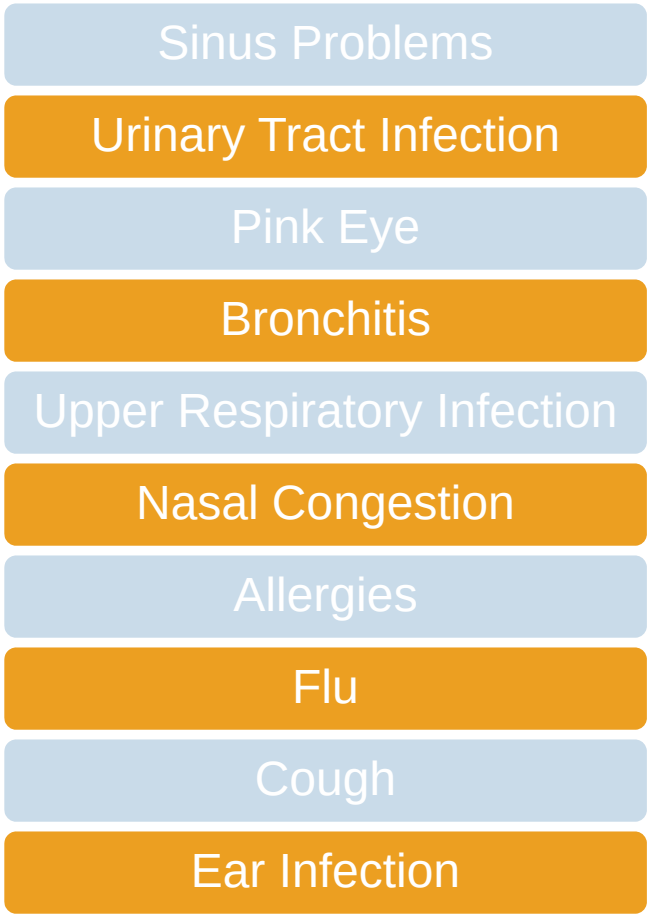
Top Diagnoses for Teleconsults



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Legal/Regulatory Issues for Telehealth Providers

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Licensure

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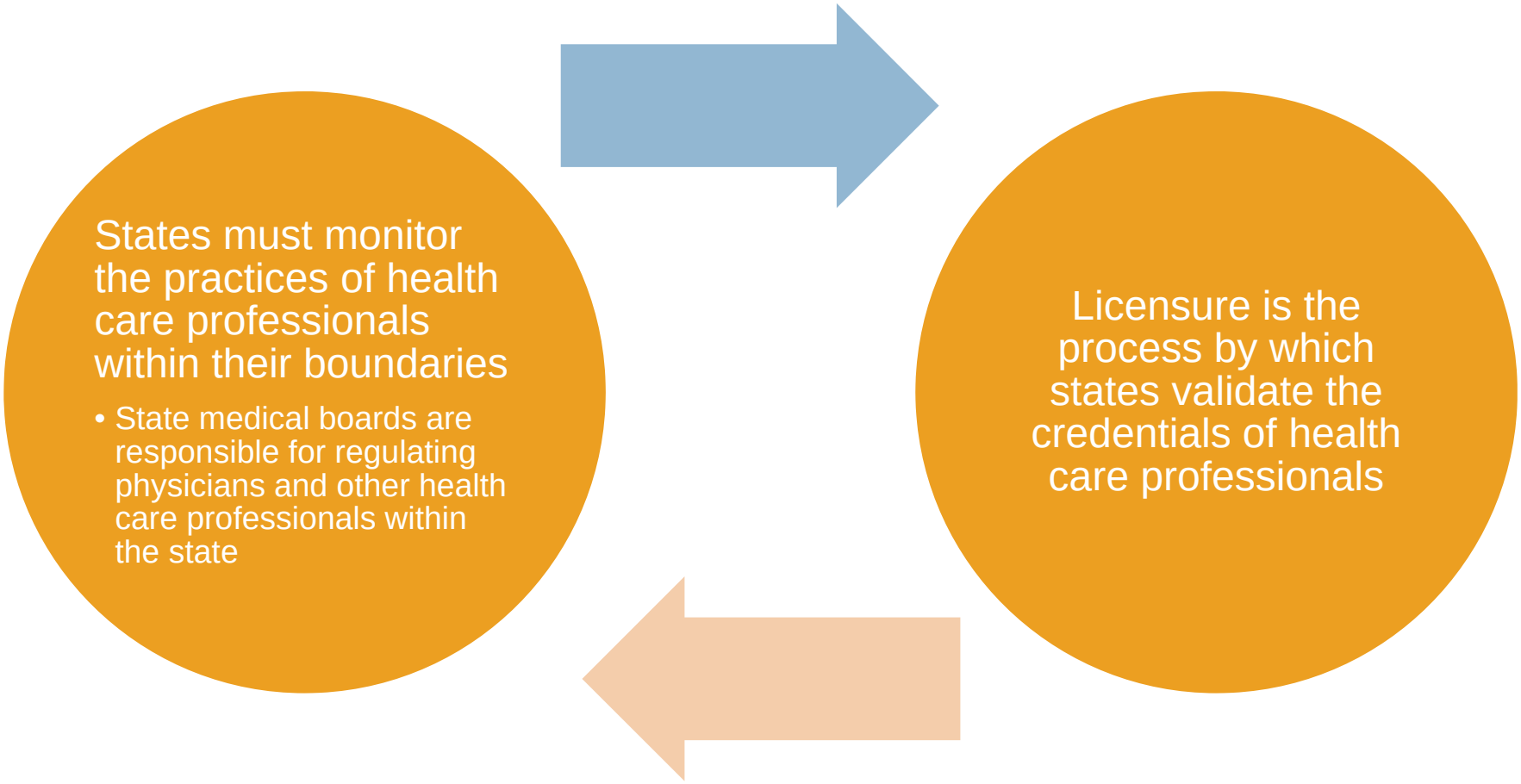
Licensure



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Licensure

State licensure rules run counter to the practice of telehealth, which transcends geographical boundaries

Health care practitioners who practice telehealth are subject to the licensure rules of the states in which the patient is physically located and where the practitioner is licensed

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Types of Licenses Available to Telemedicine Providers

Regular Licenses

- Some states require telemedicine providers to obtain the relevant professional license required by the state ***and*** to meet other related state-specific requirements such as payment of licensure fees and passage of professional examinations
  - Examples: Alaska, Connecticut, Florida, Illinois, Massachusetts

Special Telemedicine Licenses

- Some states issue special licenses / certificates related to the practice of telemedicine services, allowing out-of-state providers holding such licenses to render services provided certain conditions are met, such as not opening an office in the state
  - 10 states

Licenses for Non-Physician Practitioners

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Telemedicine Licensing Exceptions

Endorsement

- Allows out-of-state licensed physicians to obtain in-state licenses based on their out-of-state credentials
- A state board accepts the license granted by another state with similar standards
  - Examples include Arizona (Ariz. Rev. Stat. § 32-1426); Florida (Fla. Stat. § 458.313); Ohio (Ohio. Rev. Coded Ann. § 4731-6-16)

Registration

- Allows out-of-state licensed physicians to register with in-state medical licensing boards, rather than obtaining an additional in-state license

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Telemedicine Licensing Exceptions

Reciprocity

- Specific agreements between state licensing boards to mutually recognize out-of-state licenses for the purpose of in-state practice; usually created between states that have similar medical licensing laws or have agreed to harmonize their laws

"Bordering States" Exception

- Permits, under certain circumstances, the in-state practice of medicine by out-of-state physicians who are licensed by bordering states

Consultation

- Next slide

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Telemedicine Licensing Exceptions – Consultation Exception

- Available in many states
- Allows a physician who is not licensed in the state to practice medicine "in consultation" with a referring physician who is licensed in the state
  - Unclear whether the exception applies to routine, ongoing consultations with telemedicine providers
- Scope varies from state to state
  - About 25 states allow consultation with limited restriction
    - California
    - Florida
    - Hawaii
    - Illinois
    - Louisiana
    - New Jersey
    - New York
    - Pennsylvania

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Telemedicine Licensing Exceptions – Consultation Exception

- "Limited restriction" is defined to include one or more of the following:
  - Consultation must be with an in-state physician;
  - Consultation must be at the request of an in-state physician;
  - Out-of-state physician may not open up an office to see patients/receive calls in the state; and
  - In-state physician must maintain ultimate responsibility for the primary diagnosis and/or treatment of the patient

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Telemedicine Licensing Exceptions – Consultation Exception

About 20 or so states only permit consultation if provide on an infrequent basis

- Arizona - limited to actual single or infrequent consultation regarding a special patient or patients
- Delaware - limited to 12 consultations per year
- Iowa - limited to cases where the out-of-state physician is incidentally called into Iowa for consultation, defined as no more than 10 consecutive days and no more than 20 days in a year
- Maine - limited to consultation on an irregular basis
- Texas - out-of-state medical specialist may provide episodic consultation via telemedicine per the request of a Texas physician in the same medical specialty without obtaining telemedicine licensure

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Telemedicine Licensing Exceptions – Consultation Exception

- A very small number of states severely limit consultation
  - Michigan - consultation by an out-of-state physician only permitted in "exceptional circumstances" (which does not appear to be defined)
  - Rhode Island - has a general consultation exception, but it appears that out-of-state physicians must obtain a Rhode Island license before providing telemedicine services in the state (even if they are just providing consultation)

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FSMB Interstate Medical Licensure Compact

- Designed to facilitate physician licensure portability and the practice of interstate telemedicine services (http://www.fsmb.org/state-medical-boards/interstate-model-compact/)
- Would create an additional licensure pathway through which physicians could obtain expedited licensure in Compact-participating states
- Intended to complement existing licensing and regulatory authority of state medical boards
- Conceptually similar to the Nurse Licensure Compact (https://www.ncsbn.org/nlc.htm)

Federation of STATE MEDICAL BOARDS

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Licensure – Non-Physicians

- Nurse Licensure Compact
  - Allows a nurse (RN and LPN/VN) to have one compact license in the nurse's primary state of residence (the home state) and to practice in other compact states (remote states)
  - Nurse must follow the nurse practice act of each state
  - Nurse could be subject to the discipline process in the states of practice
  - Permits practice (physically and telephonically/electronically) across state lines in Compact states
  - Advanced practice registered nurses not included in this compact
- Other non-physician practitioners face same licensure issues as physicians

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Prescribing and Scope of Practice

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Online Prescribing

- States have different approaches
  - Require an in-person evaluation or physical examination before prescribing online
    - Some states explicitly require an in-person exam (*e.g.*, AR, NE)
    - Other states are not so explicit (can physical exam be provided by other means?)(*e.g.*, NJ, OR, SC)
  - Permit physicians to prescribe via telehealth only if there is a preexisting patient relationship even if physician is licensed in the state where patient is physically located
  - Many states prohibit prescribing based solely on information from an online questionnaire
  - Some states regulate online prescribing through pharmacy laws
  - A few states are liberalizing prescribing laws (*e.g.*, VA)

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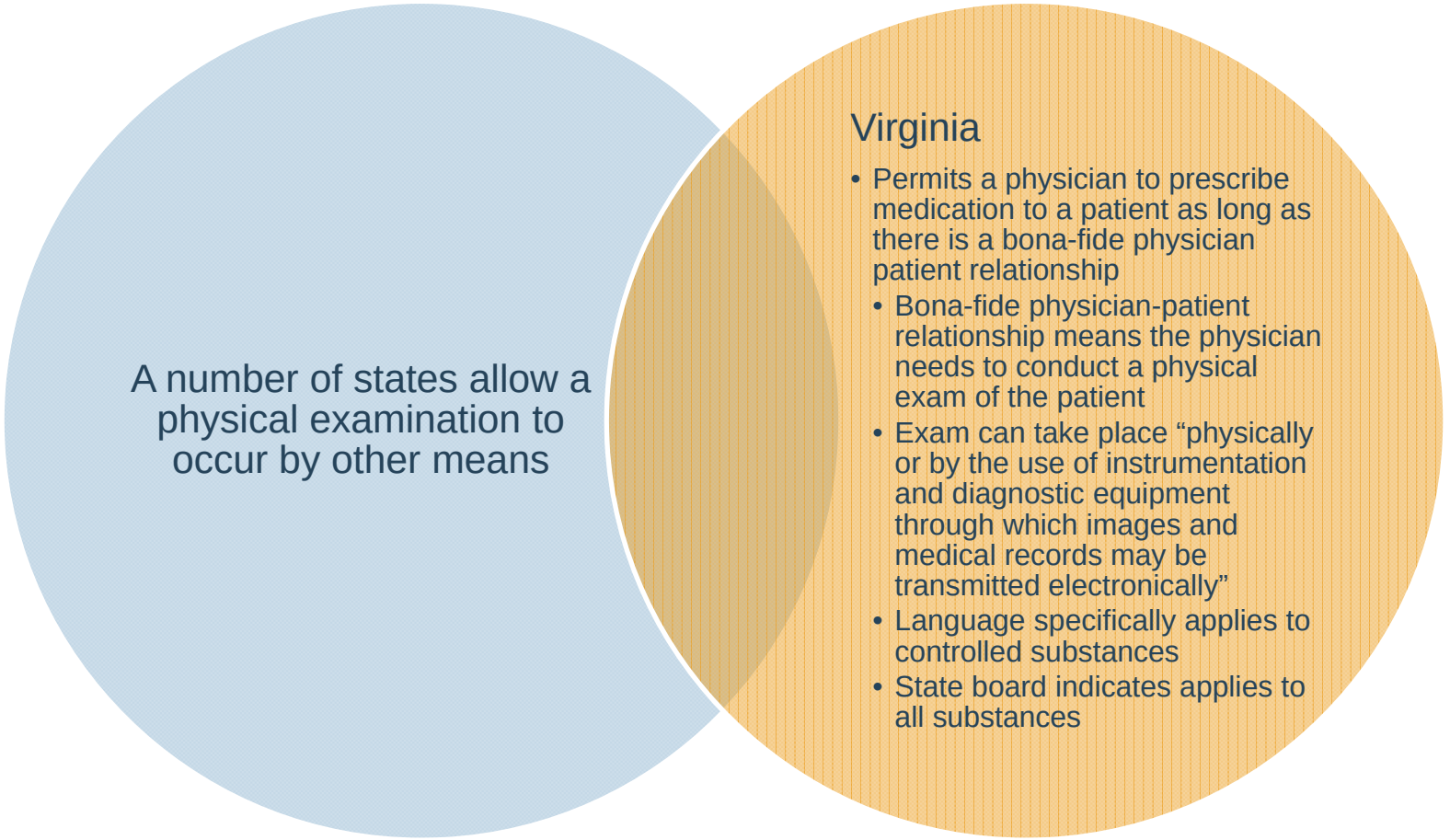
Exam by Other Means



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Exam by Other Means

Maryland

- If no prior in-person, face-to-face interaction with a patient, the physician can "incorporate real-time auditory communications or real-time visual and auditory communications to allow a free exchange of information between the patient and the physician performing the patient evaluation"

Vermont

- Provider may prescribe or provide treatment recommendations to a patient after having performed an appropriate examination of the patient either in person or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically

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Pharmacy Laws

Colorado

- Pharmacist cannot dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship

DC

- Pharmacist cannot "dispense a prescription if the pharmacist knows that the prescription was issued without a valid patient-practitioner relationship."

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Medical Liability

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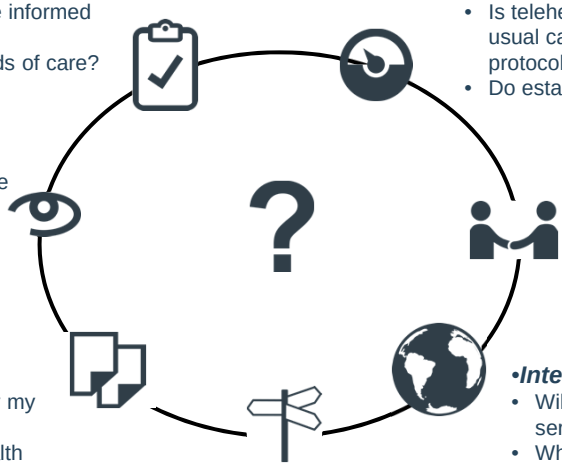
Medical Liability: Unresolved Questions

- Common medical liability questions/issues



•Telehealth Informed Consent
- Does my state require informed consent?
- What are the standards of care?

•Practice Standards and Protocols
- Is telehealth sufficiently different from usual care as to require its own protocols and standards?
- Do established guidelines exist?

•Supervision
- When is it medically appropriate to supervise other practitioners via telehealth?
- What about supervision of machines and devices that provide medical services?

•Physician-Patient Relationship
- How is it defined for purposes of scope of practice?
- How is defined in relation to liability claims?

•Liability Insurance
- Is telehealth covered under my existing policy?
- What would adding telehealth entail?

•International Telehealth
- Will I be covered while providing services internationally?
- Who has jurisdiction over international telehealth?

•Telehealth Industry
- Is telehealth **changing the nature of the relationship** between patients and providers?
- Is telehealth **fundamentally different** from traditional forms of medicine?

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Coverage and Reimbursement

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Medicare Coverage & Reimbursement

- Limited coverage
- Patient must be present and an encounter must involve interactive audio and video telecommunications providing real-time communication between the practitioner and the beneficiary
- Patient must be seen at certain identified originating sites (i.e., hospital, physician's office, FQHC)
  - In very rural counties
- Encounter may be performed at distant site by certain identified practitioners (i.e., physician, NP, PA)
- Only certain CPT codes reimbursed
- Beneficiary is responsible for coinsurance and deductible payments

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Medicaid Coverage

- States have the option / flexibility to determine whether to cover telehealth services and what types services to cover
- Most states provide at least some reimbursement for telehealth services
- States not required to submit a separate SPA for coverage or reimbursement of telehealth services, if they reimburse for telehealth the same way / amount they pay for face-to-face services / visits/consultations
- State is responsible for assuring access and covering face-to-face visits / examinations by "recognized" practitioners / providers in those parts of the state where telehealth is not available

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Private Payor Coverage

- Many leading private insurers provide coverage and reimbursement for telehealth, although their policies vary
- A growing number of states are enacting so-called telehealth parity statutes
  - These laws generally require health insurers to pay for services provided via telehealth the same way they would for services provided in-person
  - Almost a third of all states have enacted these statutes (including CA, GA, HI, MD, MI, OR, VA)
  - California's Telehealth Advancement of Act of 2011 became effective on January 1, 2012, and breaks down many of the barriers that prevented wider use of telehealth

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Privacy and Security

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Telehealth Privacy and Security Issues

- Sharing data and management responsibility with other providers
- Determining what should be maintained as part of the medical record
- Complying with privacy laws in multiple states (interstate telehealth)
- Incorporating telehealth risks into compliance program
- Web-based platforms (Skype, etc.) for delivery of treatment
- Transmission security
- Breach notification (verifying breaches)
- HIPAA privacy training and education for telehealth providers
- Business Associate Agreements with technical providers (non-covered entities) supporting telehealth services
- Presence of non-clinical personnel supporting telehealth services
- Distribution of *Notice of Privacy Practices* to telehealth patients

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Initiatives

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Various Initiatives

- FSMB Model Policy
  - Adopted in large measure in KY
- AMA policy on coverage/reimbursement for telemedicine
- ATA accreditation guidelines
- Various state bills, regulations, polices

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Other Issues

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Other Issues Not Addressed

- Fraud & abuse
- Credentialing & privileging
- Corporate practice of medicine
- International telehealth

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Questions

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