



PROGRAM MATERIALS
Program #29102
September 30, 2019

Introduction to Telemedicine

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Introduction to Telemedicine

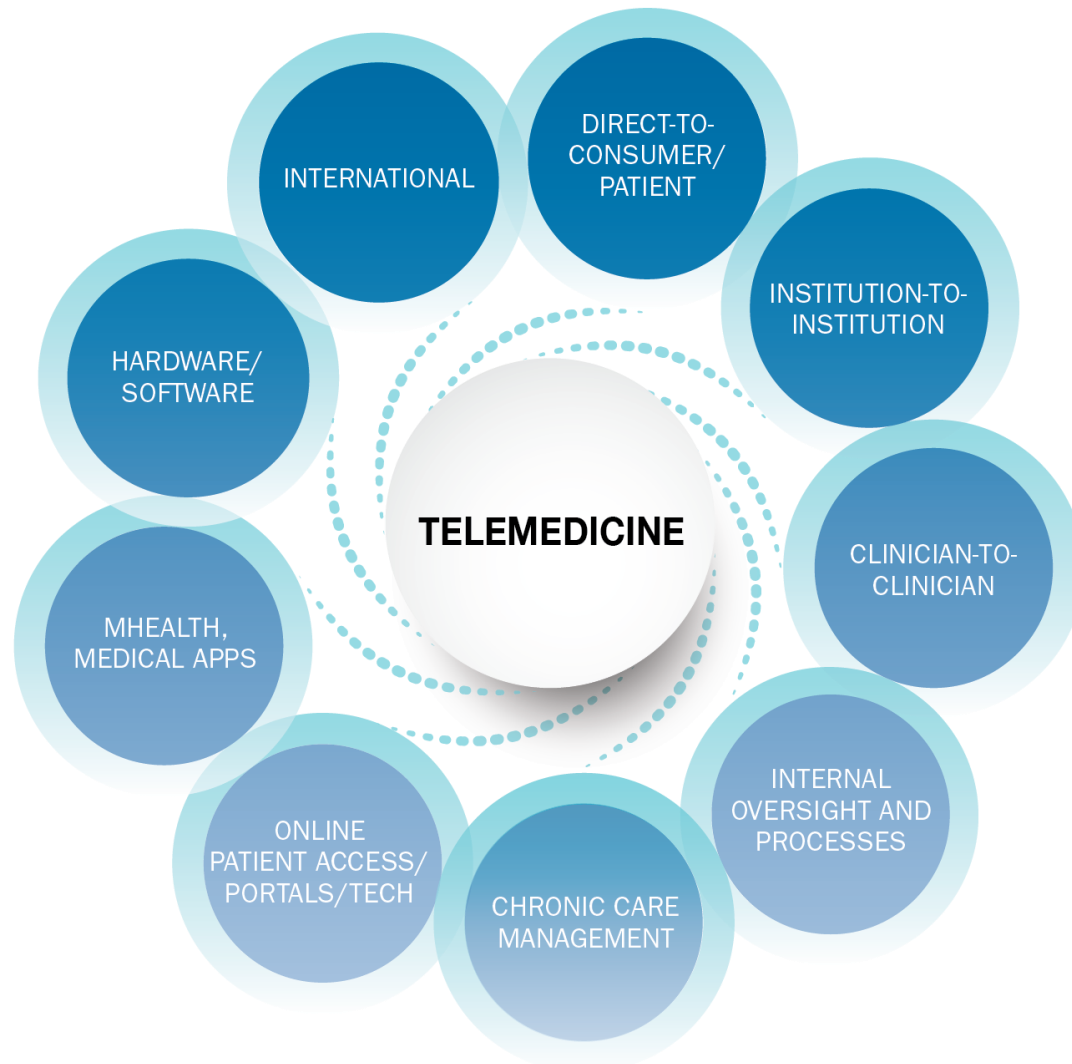
an overview of legal, regulatory,
contract and compliance issues

Kyle Y. Faget, Esq.

September 30, 2019

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Telemedicine and Digital Health



Telemedicine is Growing Even Faster Than Anticipated

Foley's 2017 Telemedicine & Digital Health Survey:
2014 vs 2017

87%

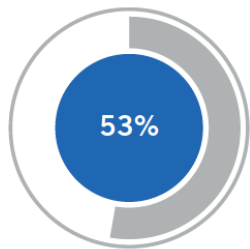
OF RESPONDENTS
TO 2014 SURVEY
DID NOT EXPECT
THEIR PATIENTS
TO BE USING
TELEMEDICINE
SERVICES.

76%

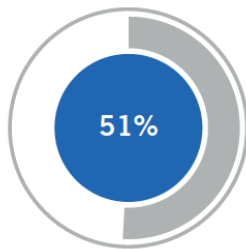
OF RESPONDENTS
TO 2017 SURVEY
OFFER OR PLAN
TO OFFER
TELEMEDICINE.

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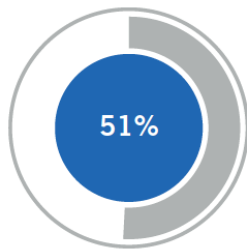
Current Perception of Opportunities in Telemedicine



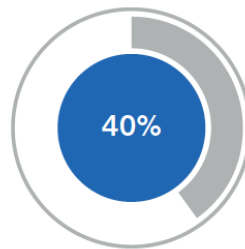
Second opinions or specialty opinions



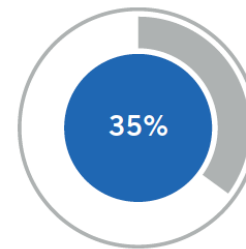
Mental health services



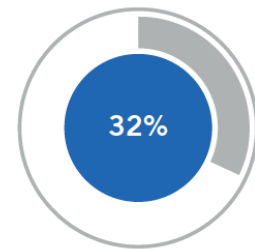
Remote patient monitoring



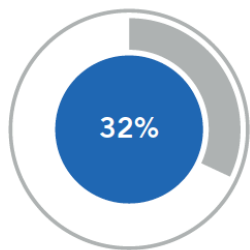
Urgent care or after-hours care



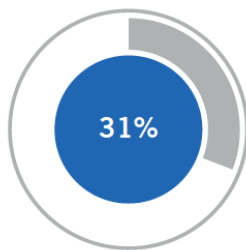
Outpatient hospital services



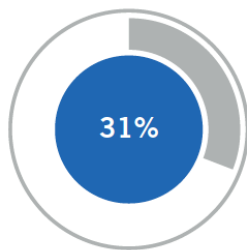
Emergency department services



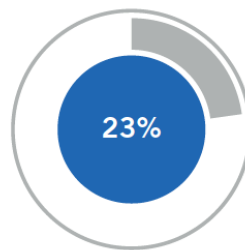
Store and forward uses (excluding radiology and pathology)



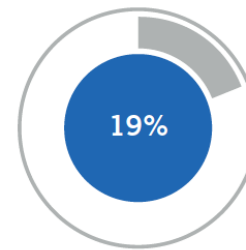
Inpatient hospital services



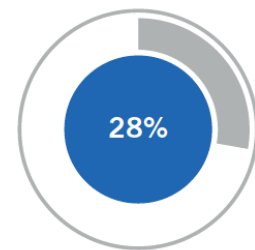
Telestroke



Destination medicine services



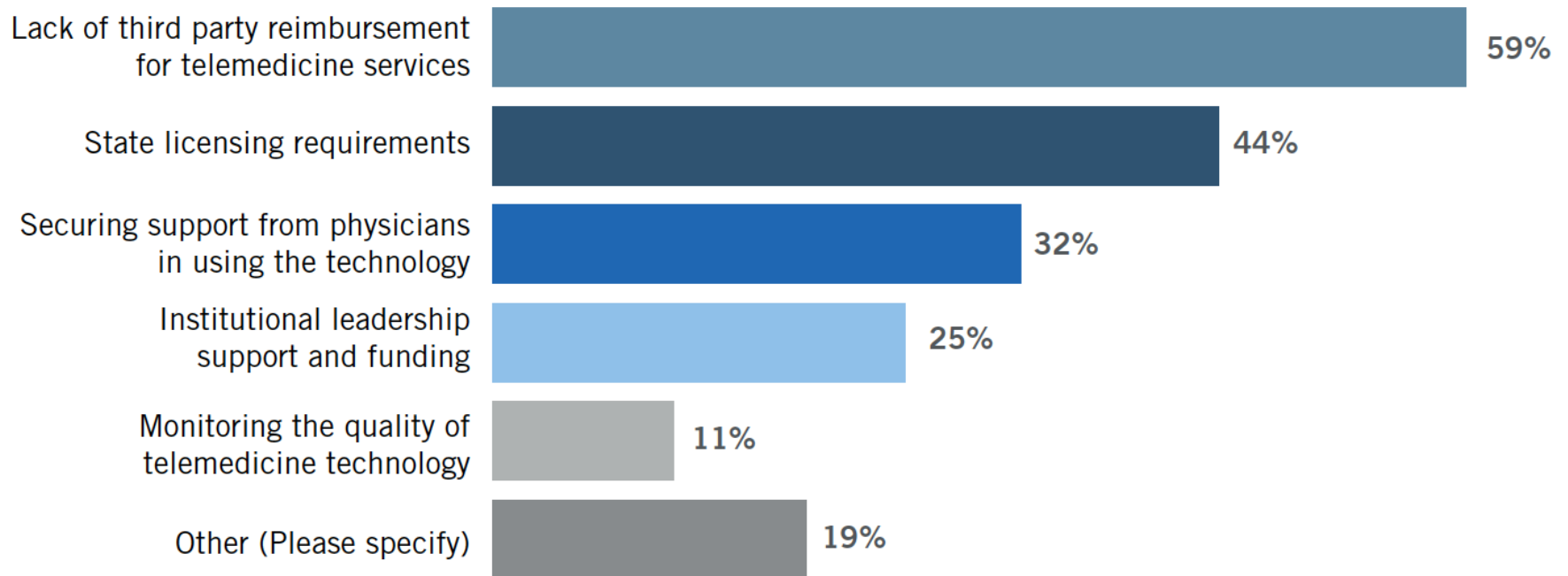
Telepharmacist



Other (please specify)

Source: Foley & Lardner 2017 Telemedicine & Digital Health Survey (Nov 2017)

Current Perception of Obstacles in Telemedicine



Source: Foley & Lardner 2017 Telemedicine & Digital Health Survey (Nov 2017)



Telemedicine and Practice Standards

Telemedicine State Practice Standards

1

New Patient vs.
Established

5

Modality of
Communication
Technology

9

Patient Choice of
Provider

2

In-Person Exam

6

Remote Prescribing
(incl. Controlled
Substances)

10

Disclosures

3

Originating Site
Restrictions

7

Record-Keeping and
Record-Sharing

11

Malpractice &
Professional
Insurance
Considerations

4

Patient-Site
Telepresenter

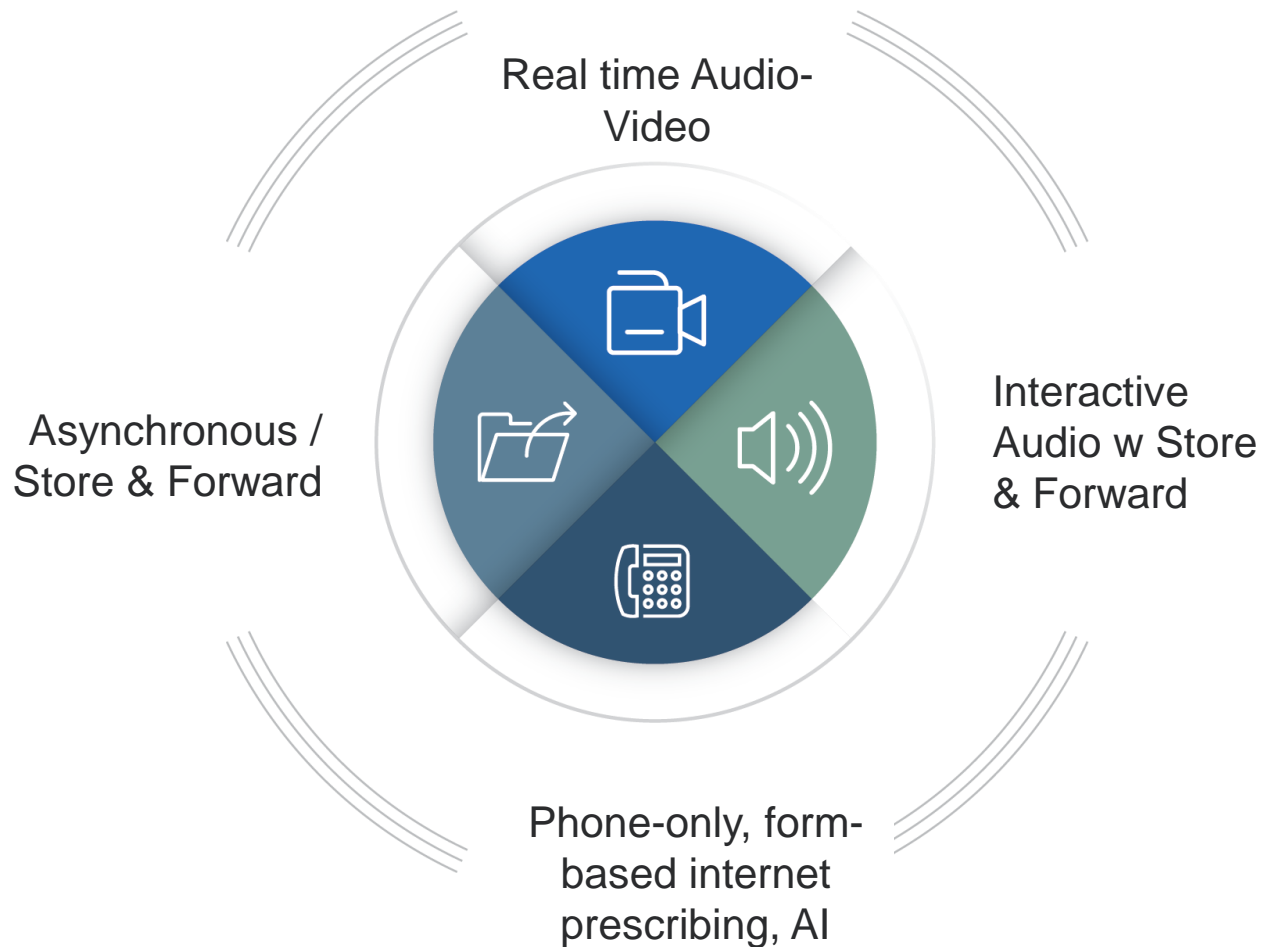
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Informed Consent

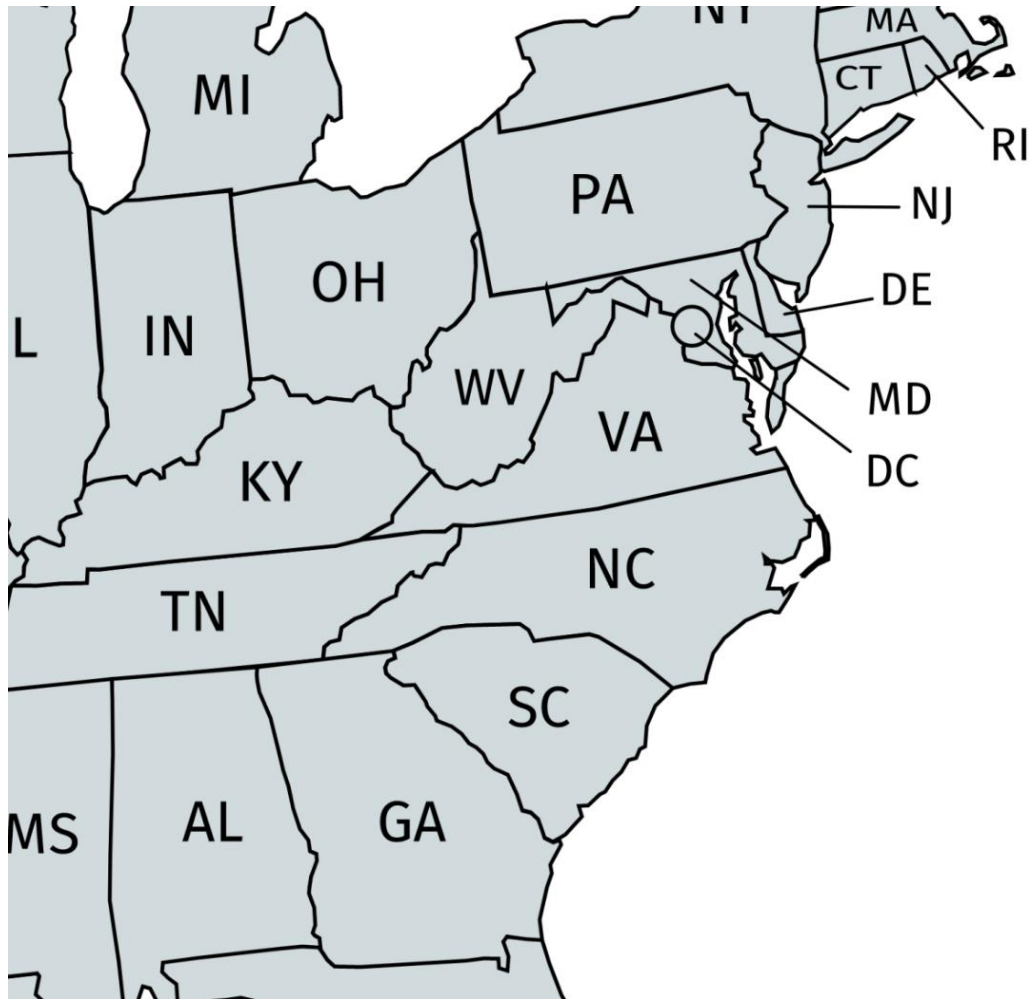
12

Credentialing

Telemedicine and Evolving Modalities

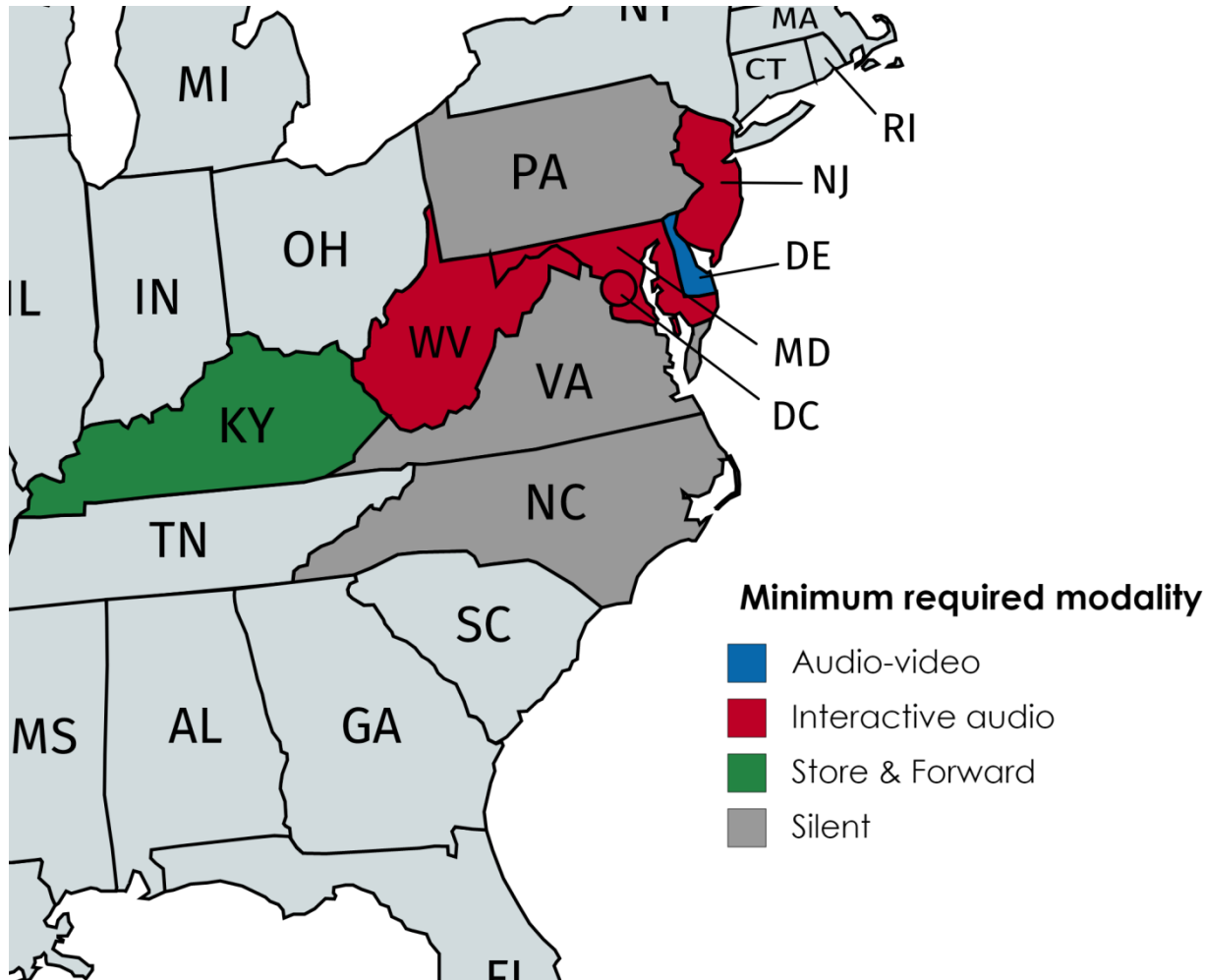


Permitted Telemedicine Modalities

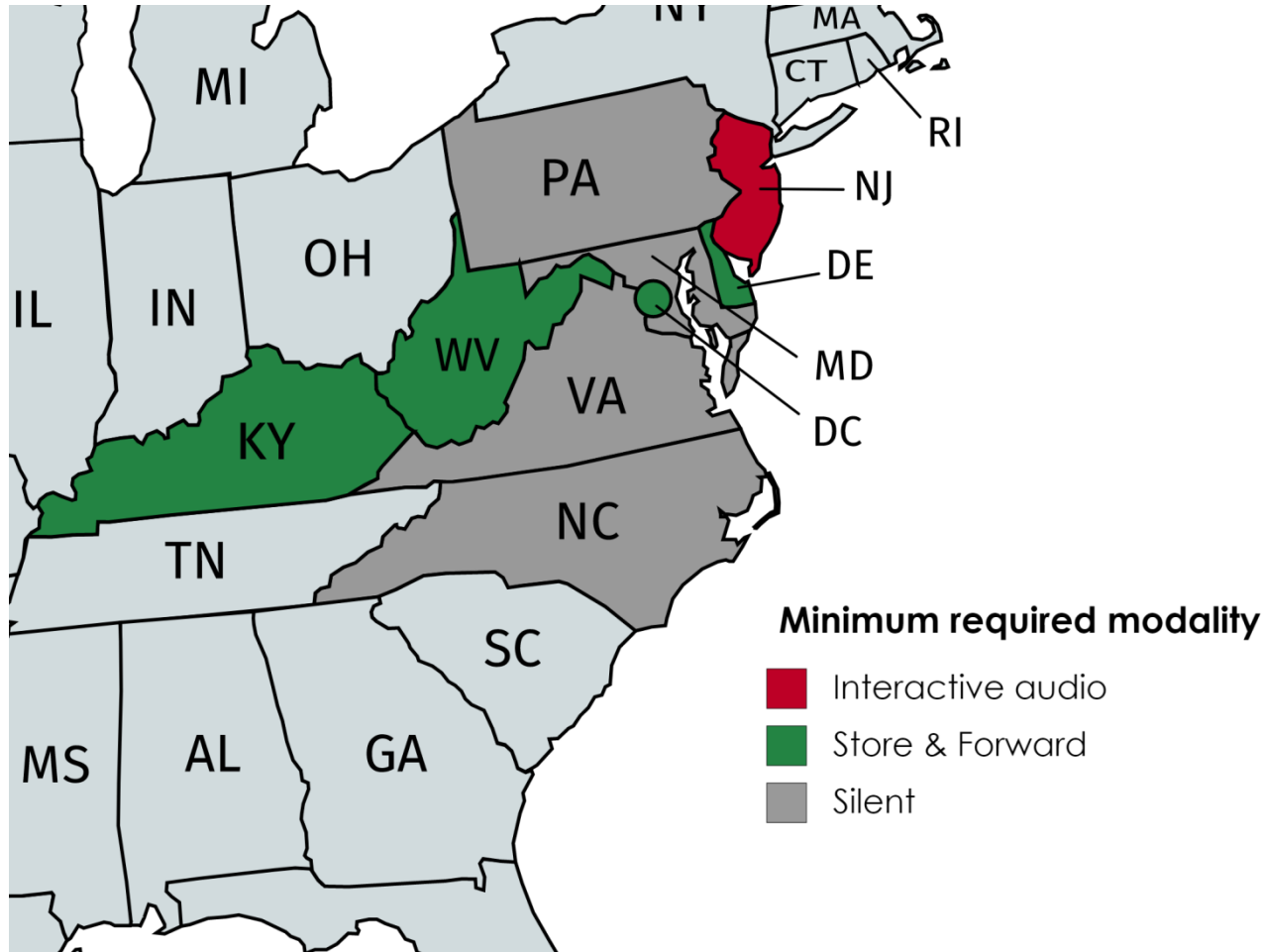


Example:
9 Mid-Atlantic States: DC, DE,
KY, MD, NC, NJ, PA, VA, WV,

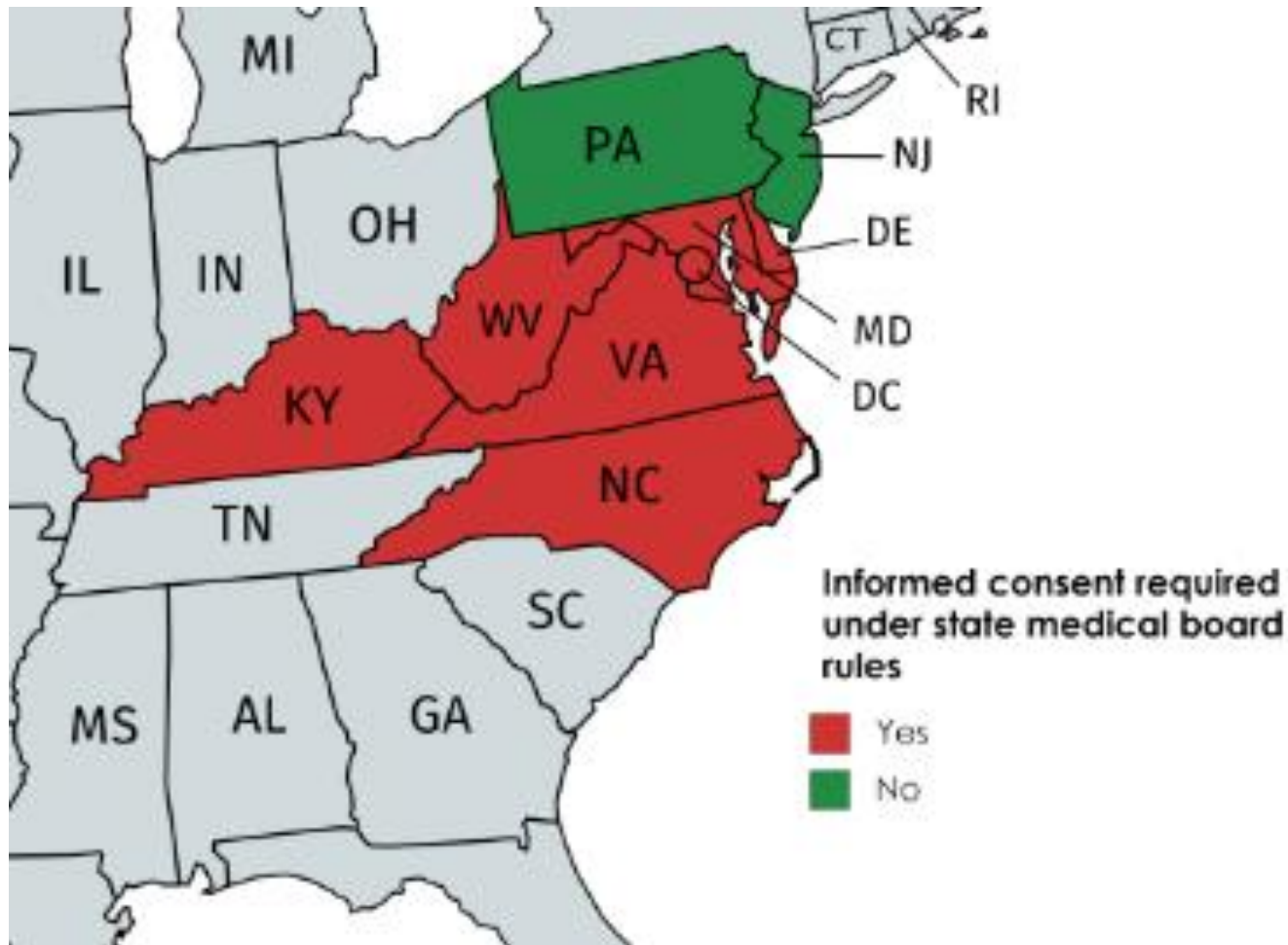
Minimum Required Modality to Create Doctor-Patient Relationship



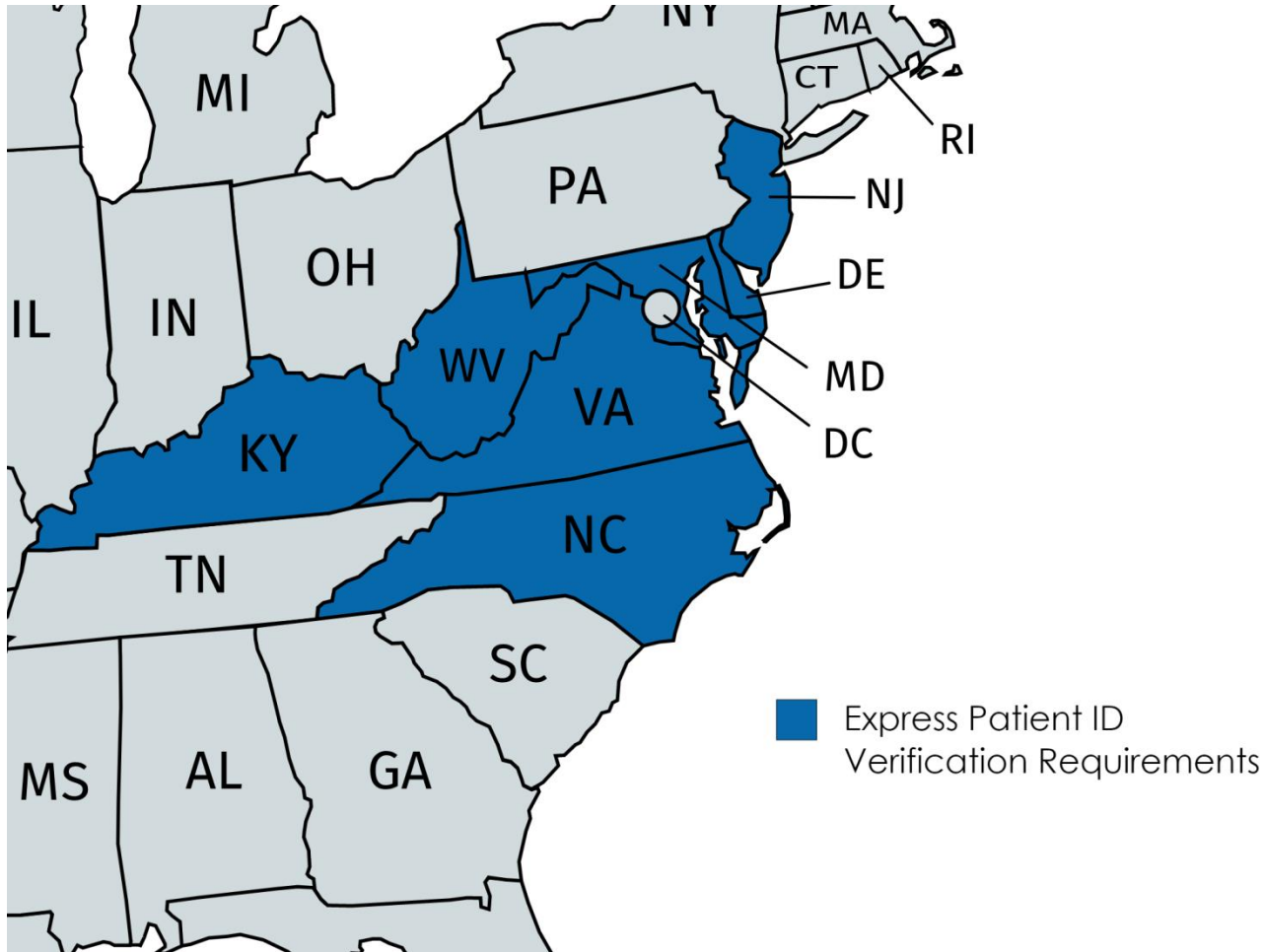
Minimum Required Modality *After Creating* Doctor-Patient Relationship



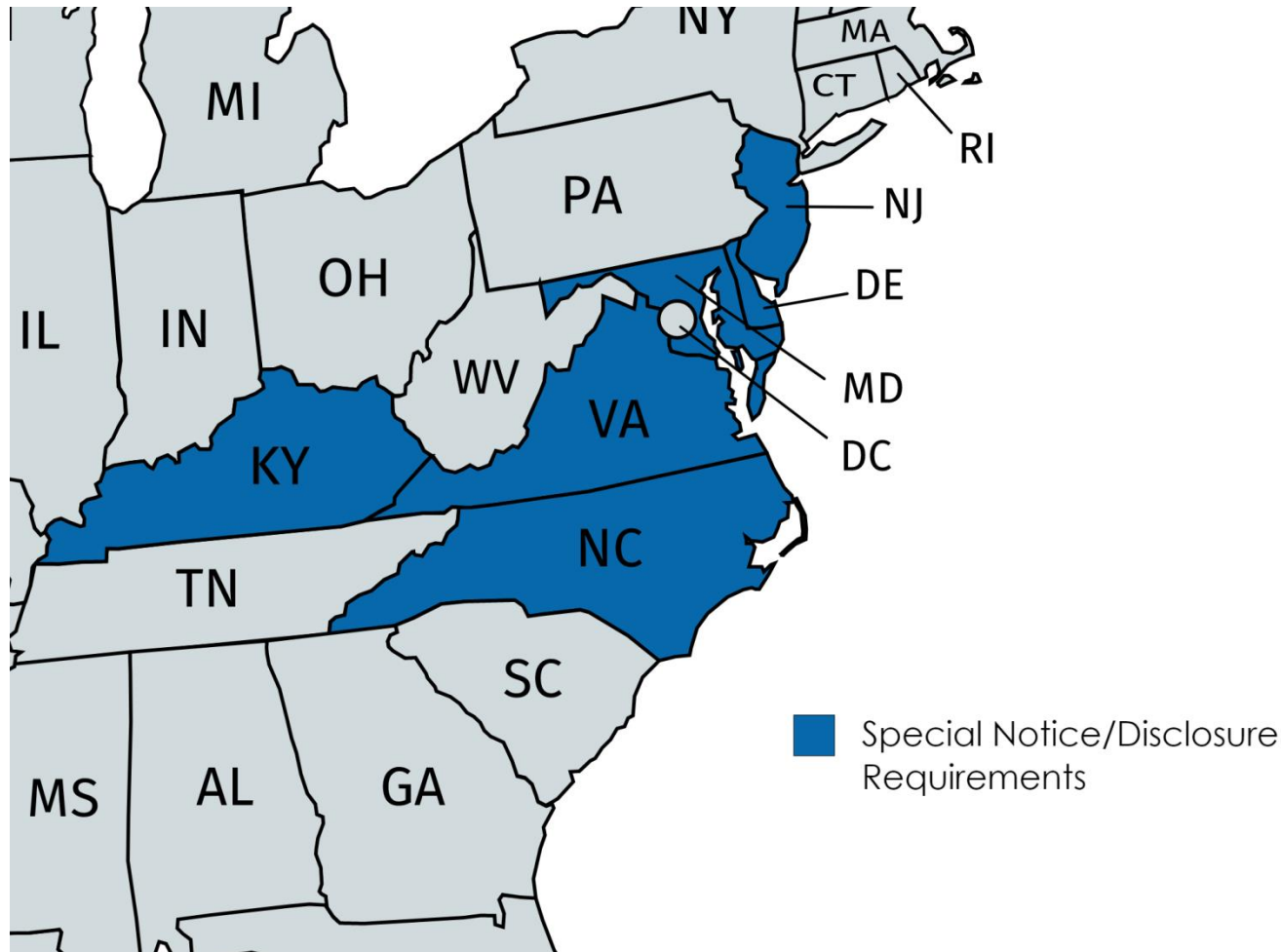
Telemedicine Patient Informed Consent Requirements



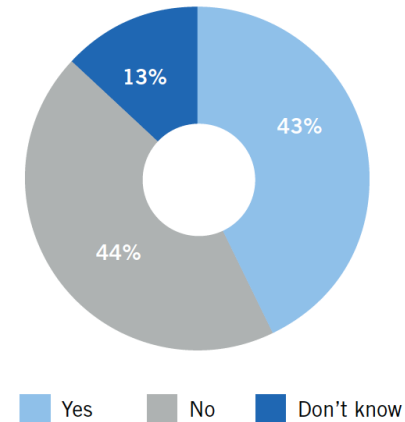
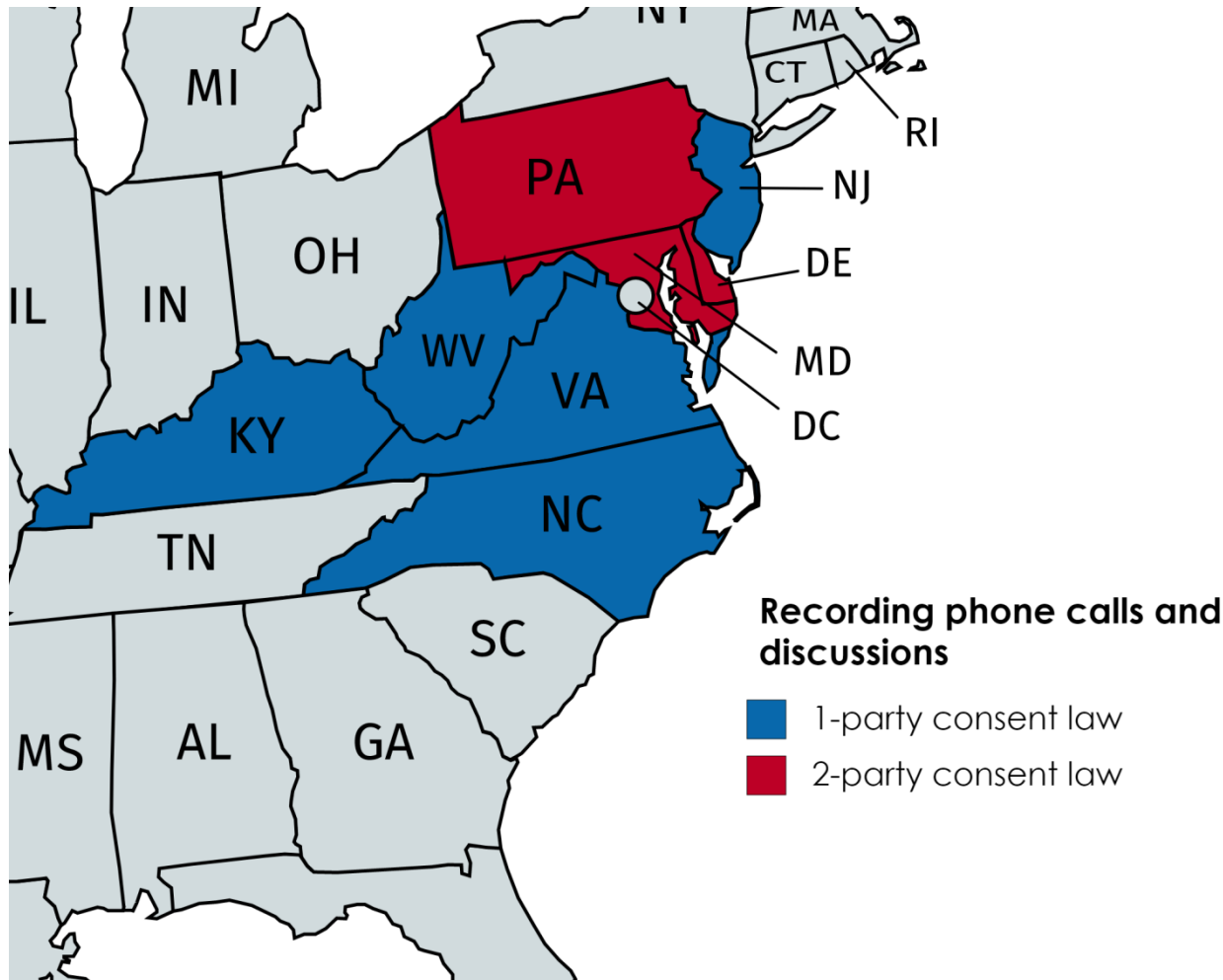
Telemedicine Patient ID Verification Requirements



Telemedicine Special Notice/Disclosure Requirements



Recording Telemedicine Consults



Source: Foley & Lardner 2017 Telemedicine & Digital Health Survey (Nov 2017)

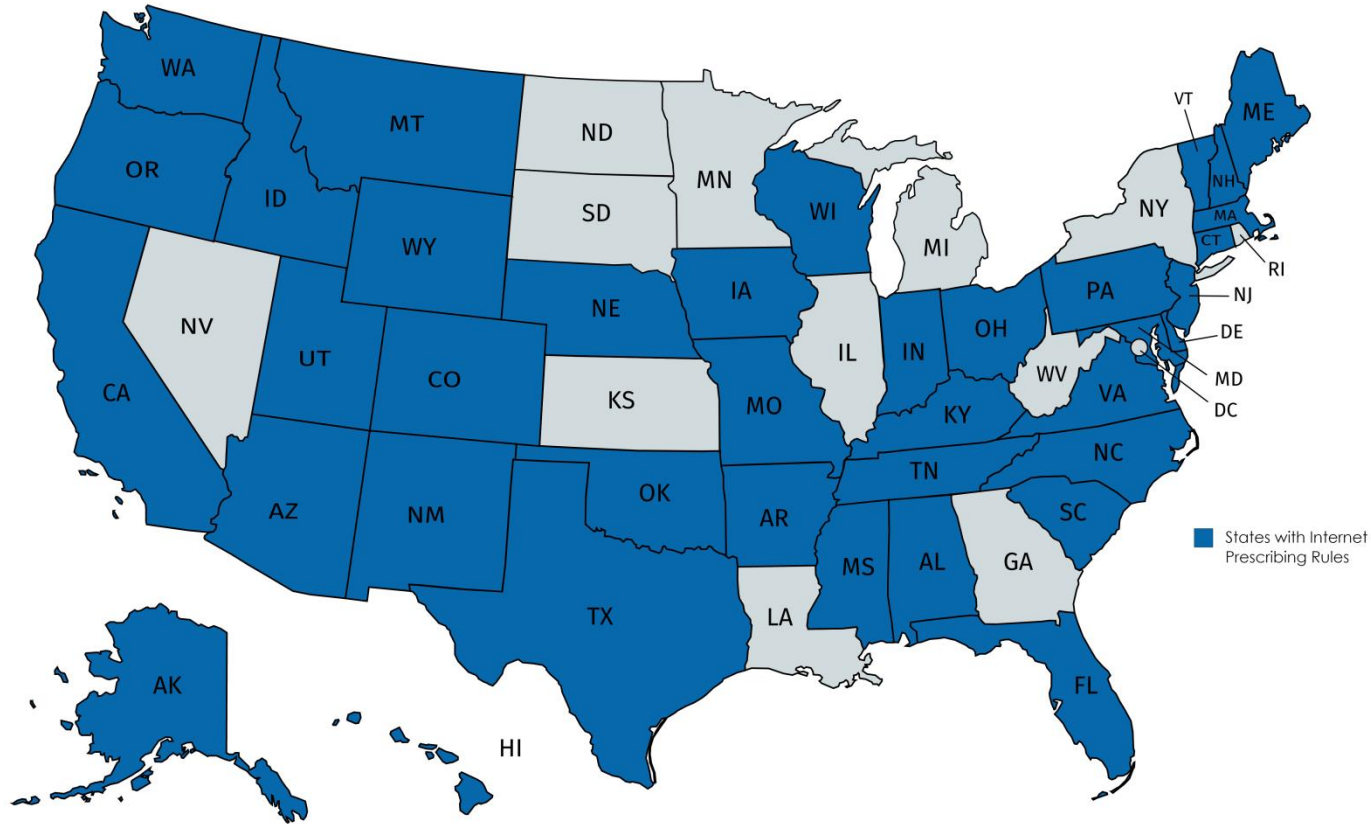


Telemedicine and Prescribing

Prescribing

- States take different approaches to remote prescribing
 - Some have rules specific to controlled substances and others have rules that apply to all prescription drugs
 - Some explicitly require an in-person or physical examination prior to prescribing
 - Some permit this exam to occur via telemedicine and others are unclear or silent
 - Many prohibit prescribing based solely on online questionnaire
 - Some regulate through Pharmacy laws
- **Federal Laws**
 - The Controlled Substances Act regulates the manufacture, importation, possession, use and distribution of controlled substances
 - DEA Registration, Prescribing Limitations
 - The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (see decision tree to right)
- **State versus Federal**
 - The federal regulations are stricter than many state laws or state medical board requirements

States with “Internet Prescribing Rules”



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Asynchronous Telemedicine vs Internet Prescribing

- Establishing provider/patient relationship
 - Tech-specific in certain states
- Practice standards impact asynchronous models
- Emphasis on clinical protocols
- Static vs. dynamic questionnaire
- Use of A.I. and algorithms
- Consumer utilization and interest increasing

Controlled Substances

- Ryan Haight Act
 - Federal prohibition on form-only online prescribing for controlled substances (CS)
 - Per se violation of the Controlled Substances Act for a physician to prescribe a CS via the internet absent at least one in-person medical exam, except in certain, specified circumstances

Ryan Haight Act

- Does not prohibit use of telemedicine to prescribe CS if federal and state requirements are met.
- Exceptions to in-person evaluation requirement.
- Practice of telemedicine exceptions.
 - Treatment in hospital or clinic
 - Treatment in physical presence of a physician
 - Special registration
 - Public health emergency
 - Indian health service/tribal organization
 - Dept. of Veteran Affairs medical emergency

Changes / Legislation

- **Special Registration for Telemedicine Clarification Act of 2018**
 - Amends the Controlled Substances Act to establish a deadline for the Drug Enforcement Administration to promulgate regulations for the special registration of practitioners to practice telemedicine.
 - Directs the AG, with the Secretary of HHS, to, within 30 days of passage of the Act, promulgate interim final regulations governing the issuance to practitioners of a special registration relating to the practice of telemedicine.
 - Special registration would allow practitioners to use telemedicine to prescribe controlled substances without the *per se* in-person exam.

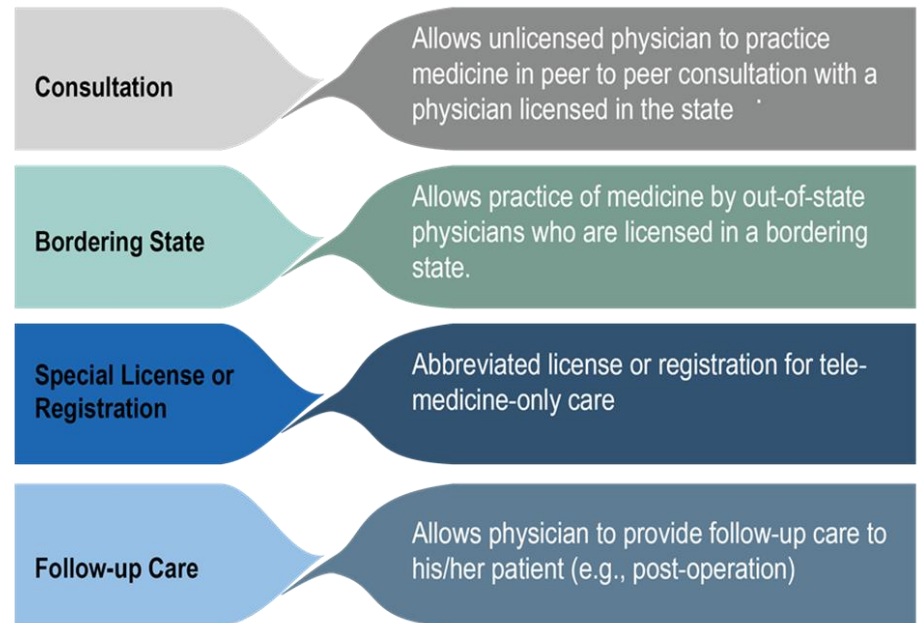


Telemedicine and Licensure

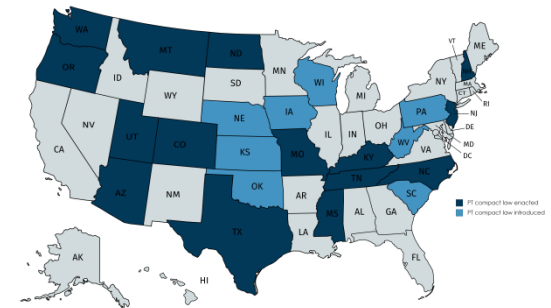
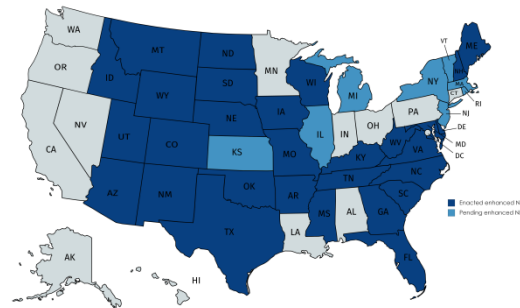
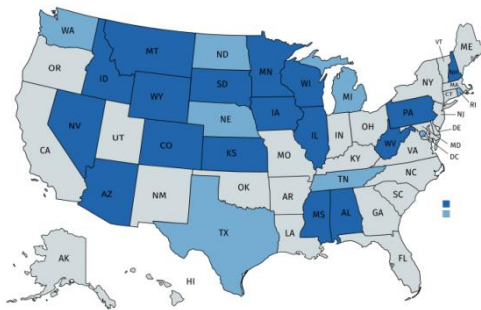
Telemedicine and Licensing

- Physician offering care via telemedicine is subject to licensure rules of the state in which the patient is physically located at the time of the consult.
- State law expressly or implicitly requires licensure if the patient is located in the state at the time of the consult.

Notable Exceptions for Telemedicine



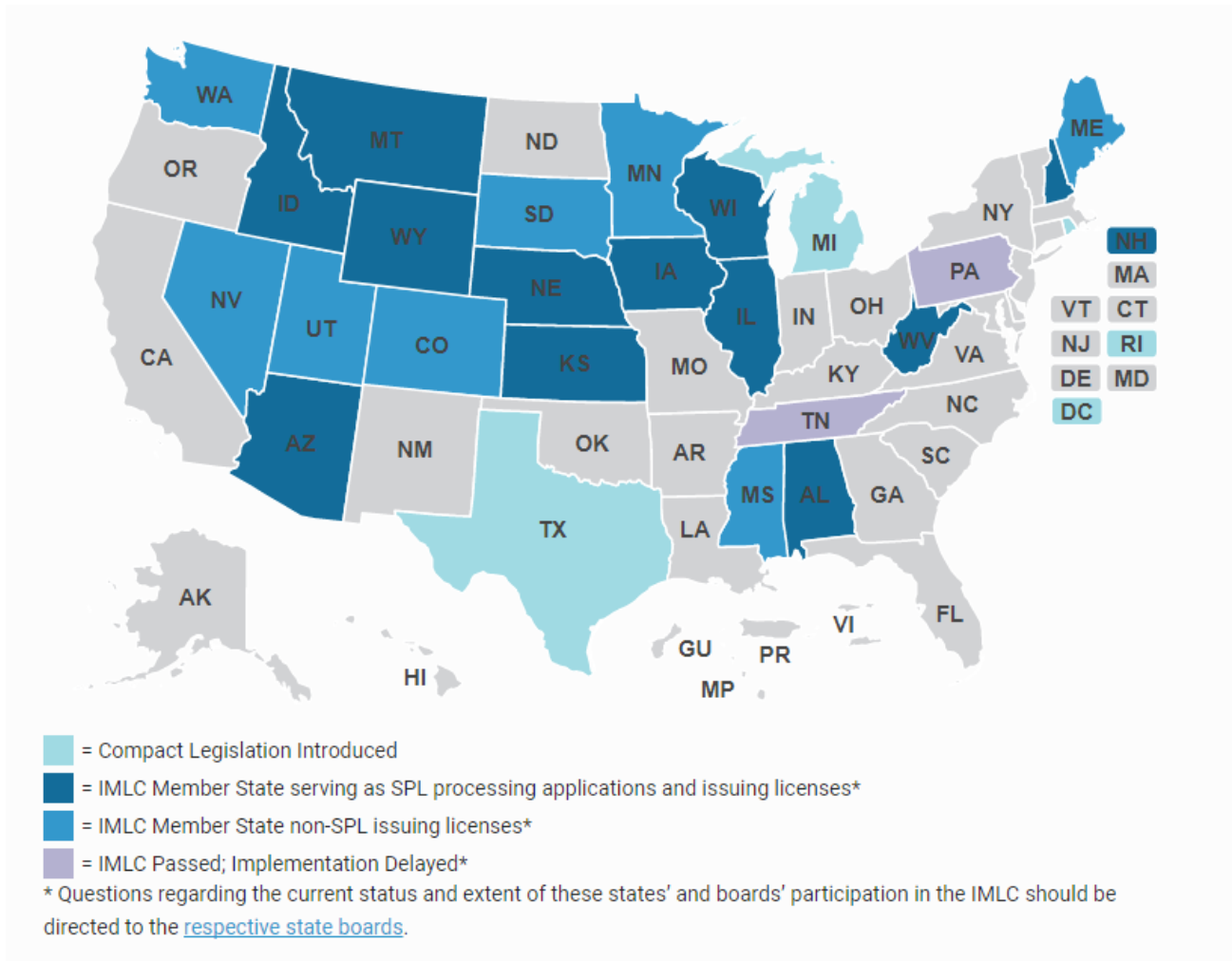
Growth of Interstate Licensing Compacts



Interstate Medical Licensure Compact

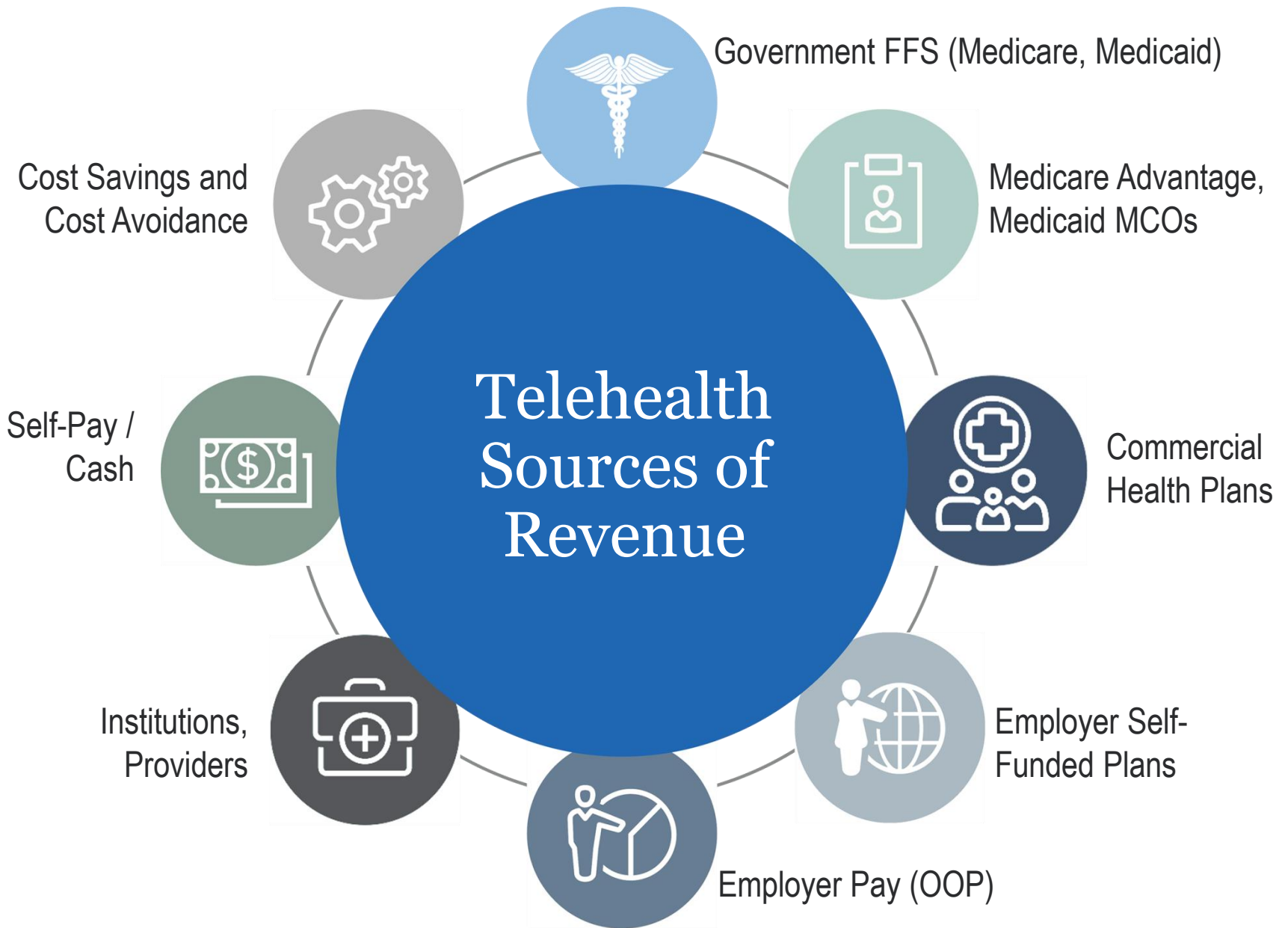
- Offers an expedited pathway to licensure for qualified physicians who wish to practice in multiple states.
- The IMLC is an agreement between states and the Medical and Osteopathic Boards in those states.
- Licensed physicians can qualify to practice medicine across state lines within the Compact if they meet the agreed upon eligibility requirements.

Licensing Policy Changes





Telehealth Payment and Reimbursement



What Are the Sources of Payment?

Medicaid FFS

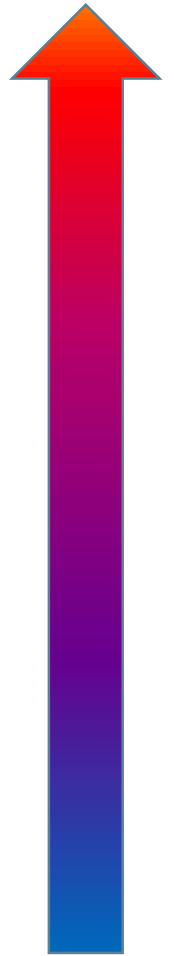
Medicare FFS

Medicaid Managed Care

Medicare Advantage

Commercial Insurance (incl. employer-pay)

Self-Payment (retail medicine)



Telehealth and Medicare

1. Patient in a qualifying rural area
2. Patient at one of eight qualifying facilities (“originating site”)
3. Service provided by one of ten eligible professionals (“distant site practitioner”)
4. Technology is real-time audio-video (interactive audio and video telecommunications system that permits real-time communication between the beneficiary and the distant site provider)
5. The service is among the list of CPT/HCPCS codes covered by Medicare

Originating Site

- An originating site is the location where a Medicare beneficiary gets physician or practitioner medical services through a telecommunications system. The beneficiary must go to the originating site for the services located in either:
 - A county outside a Metropolitan Statistical Area
 - A rural Health Professional Shortage Area in a rural census tract
 - The Health Resources and Services Administration decides HPSAs, and the Census Bureau decides MSAs.

Note: The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act removed the originating site geographic conditions and adds an individual's home as a permissible originating telehealth services site for treatment of a substance use disorder or a co-occurring mental health disorder

Originating Sites

- Physician and practitioner offices
- Hospitals
- Critical Access Hospitals (CAHs)
- Rural Health Clinics
- Federally Qualified Health Centers
- Hospital-based or CAH-based Renal Dialysis Centers (including satellites)
- Skilled Nursing Facilities (SNFs)
- Community Mental Health Centers (CMHCs)
- Renal Dialysis Facilities
- *Homes of beneficiaries with End-Stage Renal Disease (ESRD) getting home dialysis*
- *Mobile Stroke Units*

Conditions of Payment

As a condition of payment, you must use an interactive audio and video telecommunications system that permits real-time communication between you, at the distant site, and the beneficiary, at the originating site.

Asynchronous “store and forward” technology, the transmission of medical information the physician or practitioner at the distant site reviews at a later time, is permitted only in Federal telemedicine demonstration programs in Alaska or Hawaii.

ACOs & Telemedicine

Beginning January 1, 2020 - all ACOs with a two-sided model with Medicare fee-for-service beneficiaries:

- may expand telehealth services to include the home as an eligible originating site
- would not be subject to Medicare's current telehealth originating site geographic requirements.

Medicare Advantage Plans

- Beginning 2020- MAPs may offer telehealth as a mode of delivery for any service already covered by Part B and not be subject to the original Medicare restrictions/limitations.
- Coverage of telehealth-delivered services beyond what is required by original Medicare is not mandated. MAPs are not required to offer these additional telehealth benefits.
- Services that are covered by Medicare Part B can be offered via telehealth and covered by the plan, should it choose to (note need to determine if there is an in-person component to the service).
- The MAPs will decide what additional telehealth services are covered.
- The original Medicare restrictions of geographic and facility limits do not apply.
- The modalities allowed are broadly defined

Medicaid – Varies State by State

- Live-video conferencing is the most common telehealth modality that is reimbursed, with all 50 states and DC reimbursing for live video telehealth of some form as of February 2019.
- Often many restrictions on the type of provider, facility, or service that can be reimbursed.
- Reimbursement for other forms of telehealth is less common. Store-and-forward telehealth is only reimbursed in 11 States; often restricted to certain specialties such as dermatology.
- Remote patient monitoring is reimbursed in 20 States.
- Many state Medicaid programs, like Medicare, provide a facility fee, and sometimes allow for a transmission fee to cover the cost of connecting the patient to the distant site provider

Source: Center for Connected Health Policy *Telehealth Reimbursement* (February 2019).

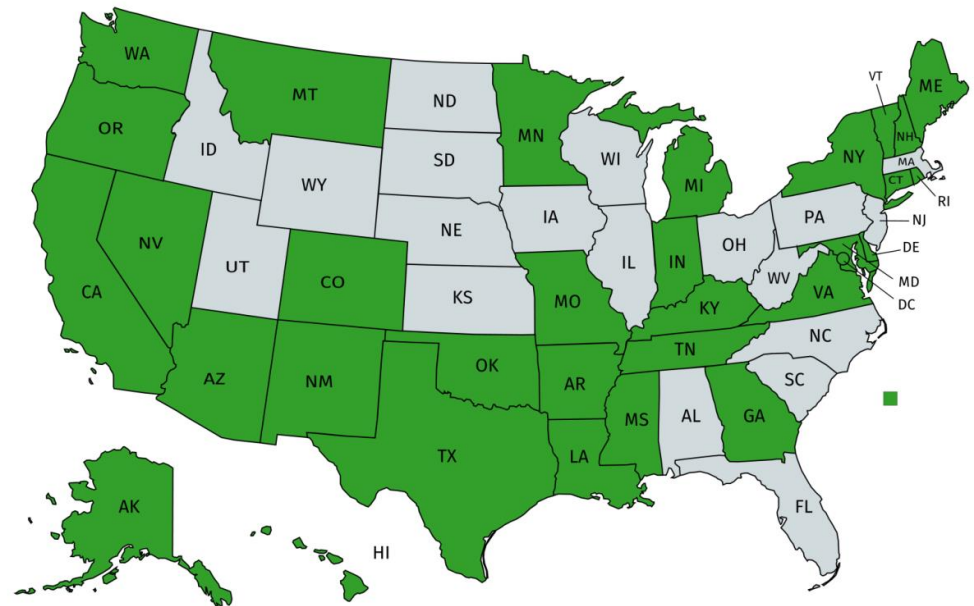
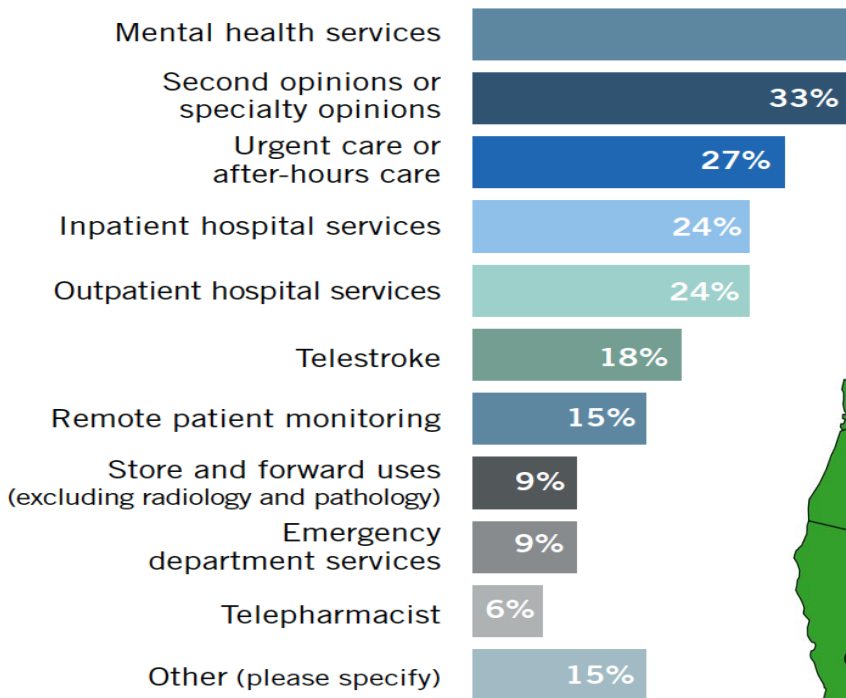
Private Payors

- No unique set of standards that pertains to insurance companies throughout the country.
- As of October 2018, 40 jurisdictions (including DC) have enacted (or will enact at a later date) laws that govern private payer telehealth reimbursement.
- In most cases, these laws offer coverage parity, requiring insurers to cover the same services delivered through telehealth, as are covered in-person, as long as it meets the same standard of care.
- Many states also make their telehealth parity laws “subject to the terms and conditions of the contract.” This phrasing may set up certain conditions where an insurer has the flexibility to restrict telehealth reimbursement within their contract.

Private Payors

- Telehealth commercial payer statutes often include information on coverage and payment parity.
- *Coverage* parity refers to the state law or rule that requires a commercial insurer to cover a health care service delivered via telemedicine if the insurer would cover the same service if it were provided during an in-person consultation.
- *Payment* parity means the state law or rule requires a commercial insurer to pay a provider for a health care service delivered via telemedicine at the same reimbursement rate as the insurer would pay for the same service if it were delivered during an in-person consultation by that same provider.

Telehealth Commercial Insurance Coverage



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Legal & Regulatory Considerations

Legal & Regulatory Considerations

U.S. Federal

- Anti-Kickback Statute
- Physician Self-Referral
- Civil Monetary Penalty Law
- Payer Rules (including Medicare, Medicaid)
- FTC, FDA, DEA

U.S. State

- Patient Brokering Acts
- Fee-Splitting Laws
- Self-Referral Laws
- Corporate Practice of Medicine
- Insurance Laws
- Supervision of NPPs
- eCommerce Considerations

International

- Foreign Corrupt Practices Act
- US Export Control Laws
- US Anti-Terrorism Laws
- US Anti-Boycott Laws
- International Corporate Laws and Tax
- Data protection; data ownership; data sharing
- Intellectual Property
- GDPR

Speaker Contact



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