

TeleMental Health Services

Overcoming Legal Hurdles

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Today's Agenda

1. Introduction
2. Legal Challenges
 - a. Licensure Requirements
 - b. Fraud and Abuse
 - c. Privacy and Security
 - d. Payment Issues
 - e. Drug Prescribing
 - f. Other State Law Considerations
3. Practical Challenges and Case Studies

Prevalence of Mental Illness

- About **half of all Americans** will meet criteria for a diagnosable psychiatric disorder in their **lifetime**.¹
- 2013 National Survey on Drug Use and Health estimates that **1 in 5 adults** aged 18 or older (18.5 percent) had a mental illness in the **past year** and only 45% received treatment.

Direct Costs of Mental Illness

- Mental illness has significant costs, but direct costs make up a relatively small portion of overall healthcare spending.
- According to SAMHSA, mental illness treatment costs are **\$100 billion** annually, accounting for **6.4%** of the **\$1.6 trillion** spent on healthcare in the US annually.

Indirect Costs of Mental Illness

- Much **higher than direct costs**.
- Estimates of the annual costs of serious mental illness are **\$193 billion in lost earnings** and **\$24 billion in disability benefits**.^{2,3}
- Mental illness causes **more days of work loss and work impairment** than many other chronic conditions such as diabetes, asthma, and arthritis.⁴

Mental and Physical Comorbidity

- There is a great deal of comorbidity between physical and mental illness.
- 68%** of mental health patients have at least one medical condition, **29%** of medical patients have a mental health condition as well.⁵
- Comorbidity is important because mental illness contributes to **increased costs for physical medicine.**

Medical Costs of Mental Illness

- One study found an **increase** of **\$505** and **\$651 pmpm** for those with depression and anxiety respectively, the **majority** was from **medical care**.⁶
- Comorbid diabetes patients perform less self-care, are less adherent, and have less preventive care.⁷
- Depression better predicts symptoms than glucose control, and diabetes patients with depression report up to **2-3x** the symptoms as those without depression.⁸

Behavioral Health Treatment Efficacy

-We have a large problem of mental illness, but we also have **effective treatment that works** when we know what we're doing.⁹

-Despite having effective treatment, there have been significant obstacles to providing patients with quality care.



USPSTF Recommendations

USPSTF says you **should screen adults and adolescents for depression** when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.



Lack of Access to Specialty Care

- US DHHS 91 million adults live in areas of **psychiatry shortage**. 55% of the nations 3,100 counties have **no practicing mental health workers**.
- There are many more primary care providers than psychiatrists. 2012 AAMC Physician Specialty Data Book- 271,106 primary care, 38,289 psychiatrists.
- Also psychiatrists are **aging out** of practice, 56.7% 55 or older vs average of 40.3%.



Lack of Access to Specialty Care

- A study was conducted in Los Angeles County¹⁰
 - 229 psychiatrists
 - 28 appts
 - median cost of \$450 for initial visit
 - wait times > 5 weeks in 80% of cases.
- 55% of psychiatrists accept insurance vs 88% of other specialties.¹¹

Lack of Access to Specialty Care

- Primary care providers feel the effects of this shortage and about $\frac{2}{3}$ of PCPs say they **can't get outpatient mental health** services for their patients.¹²
- Primary care physicians have become the de facto mental health providers.
- Psychotropics are prescribed 59% by PCPs, 23% by psychiatrists, and 19% by others.¹³

Lack of Access = Inadequate Care

- Primary care

 - 50% **not adequately diagnosed**

 - diagnosed and treated

 - 50% are **underdosed**

 - 10% get combo therapy and meds.¹⁴

- 60% received treatment, only $\frac{1}{3}$ minimally adequate¹⁵

- 80% do not receive adequate treatment.

Telemedicine

- Primary benefit is increased access.
- Breaks down barriers of distance, time, and stigma.
- Also gives providers increased freedom/flexibility and decreases stigma/overhead.



Doctor On Demand

- We provide therapy and medication and have a nationwide network of 300+ psychologists and psychiatrists.
- Also physicians available for on-demand care.



References

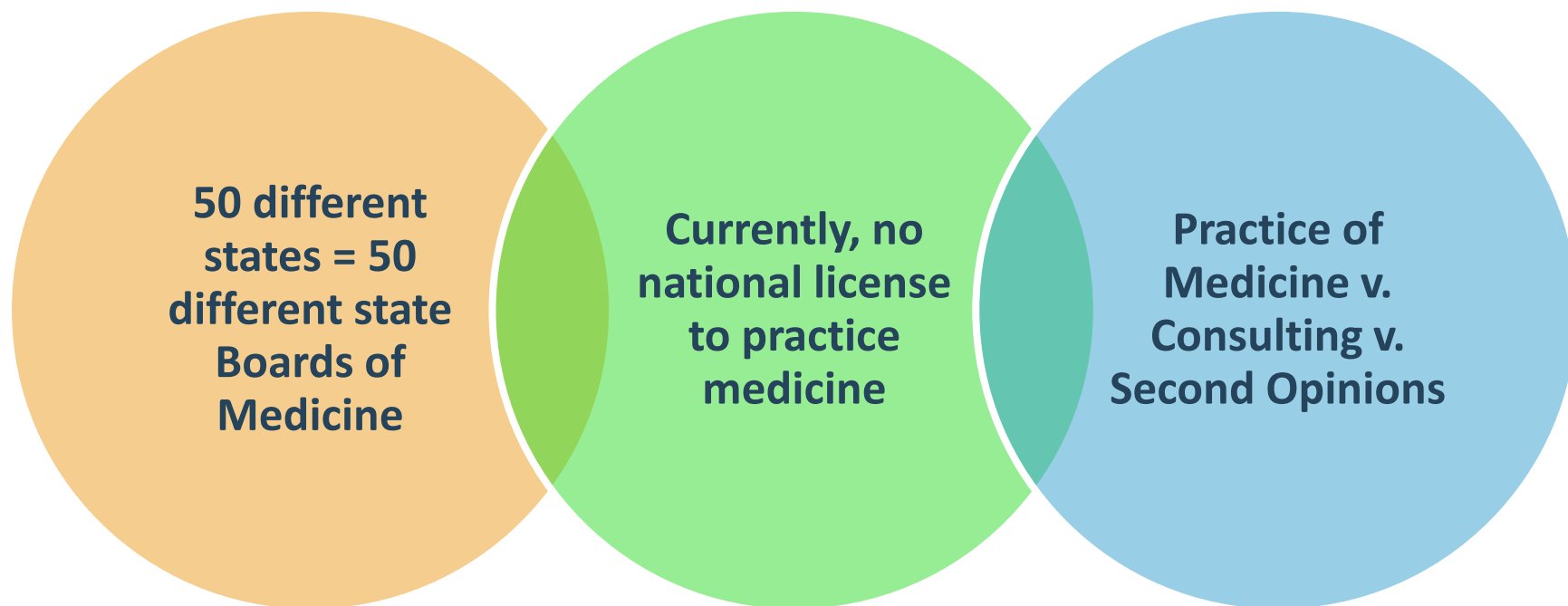
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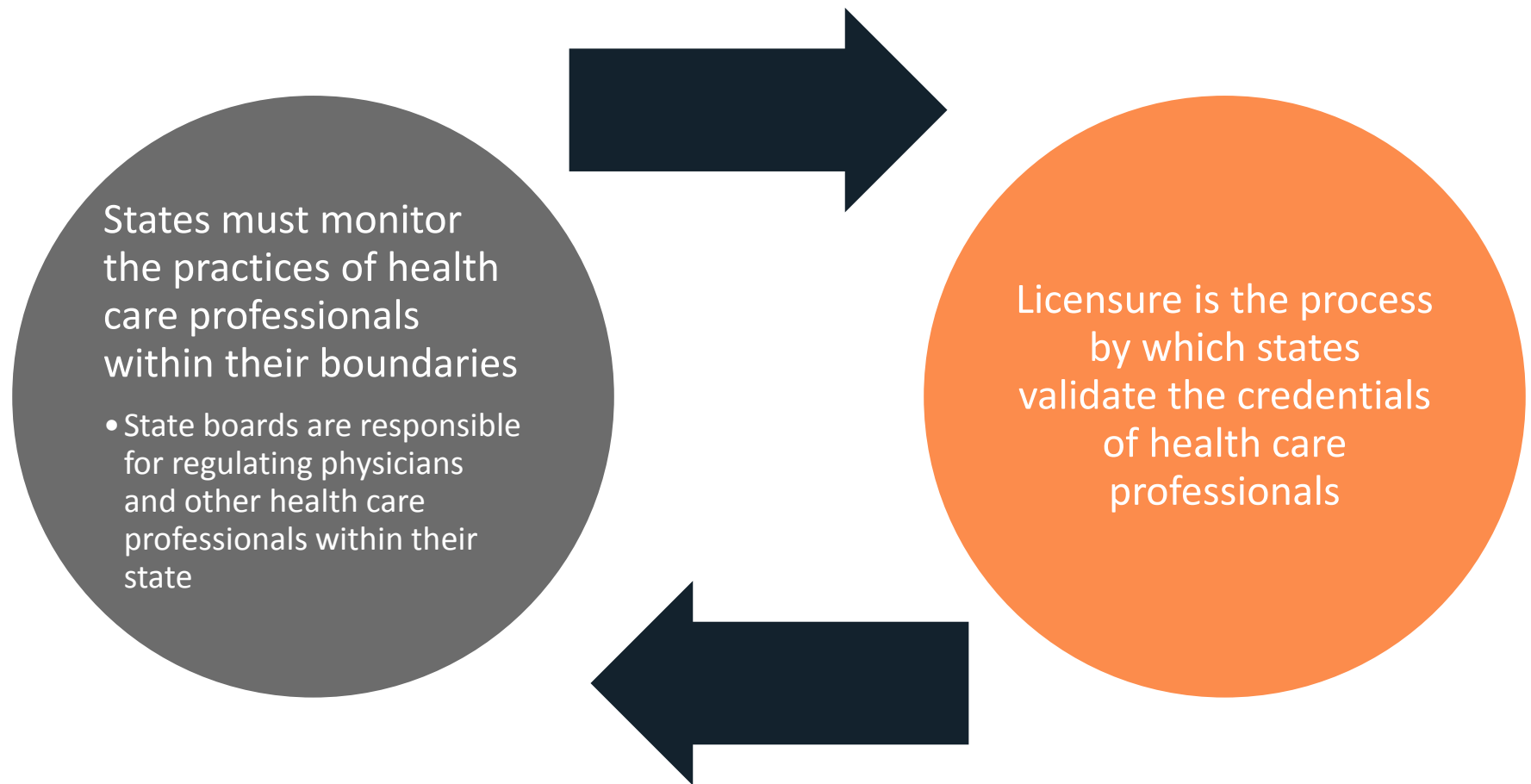
Licensure Considerations

Licensure – An Overview

“States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety, and other valid interests, they have broad power to establish standards for licensing practitioners and regulating the practice of professions.” Gade v. Nat’l Solid Waste Mgmt. Assoc., 505 U.S. 88 (1992)



Licensure – An Overview



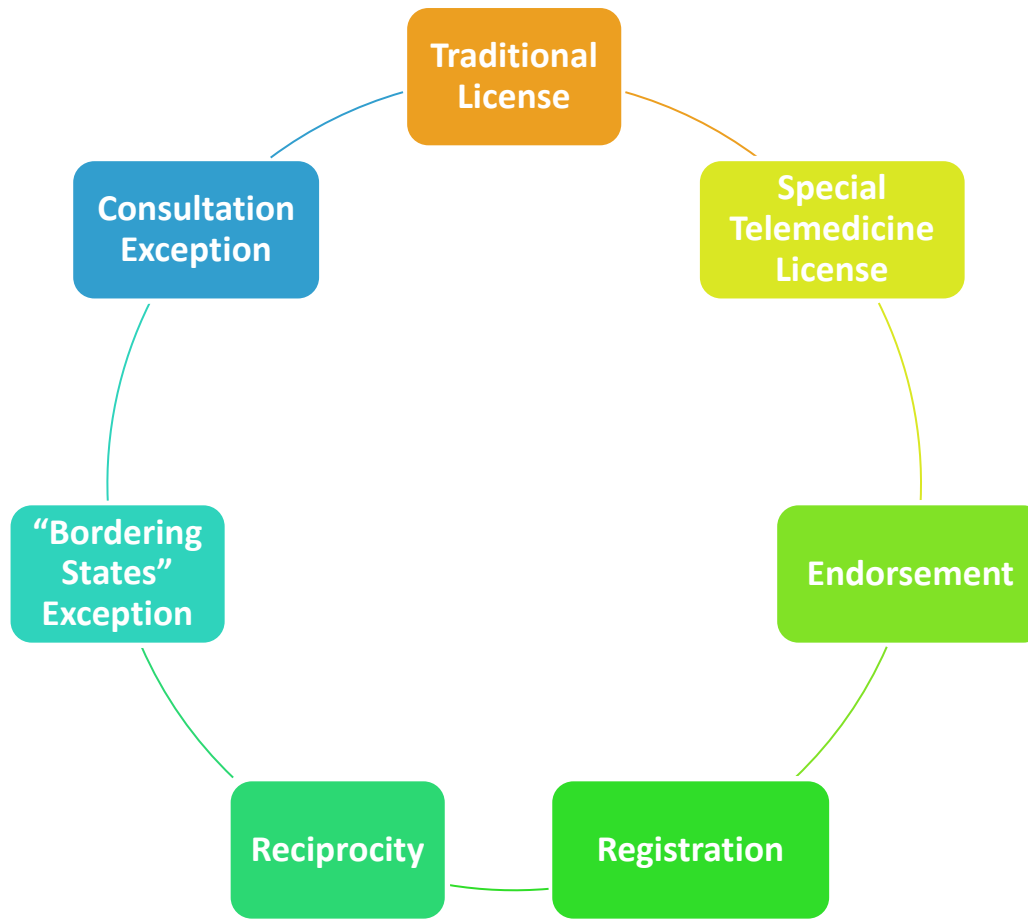
Licensure and Telehealth

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

Health care practitioners who provide services via telehealth modalities generally are subject to the licensure rules of the state in which the patient is physically located



Licensure and Telehealth



Licensure and Telehealth

Initiatives Attempting to Address Telehealth Licensure Issues

- Federation of State Medical Boards' Interstate Medical Licensure Compact
- Federal Initiatives
 - Telehealth Promotion Act (H.R. 6719, introduced Dec. 2012)
 - TELE-MED Act (H.R. 3077, introduced Sept. 2013)
- State Initiatives
 - Some states explicitly address the issue (e.g., TEX. OCC. CODE § 151.056(a))
 - Some states indirectly address the issue
 - By including the act of diagnosing or rendering treatment through “electronic or other means” as part of the practice of medicine (e.g., W. VA. CODE § 30-3-13(a))
 - By using broader language such as “by any means or instrumentality” to subject out-of-state practitioners to the state’s medical licensing laws (e.g., WIS. STAT. § 448.01(9)(a))
 - Some states do not address the issue at all

FSMB Interstate Medical Licensure Compact

- Designed to facilitate physician licensure portability and the practice of interstate telemedicine services (<http://www.licenseportability.org>)
- 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
- Currently, 12 states have adopted Compact, and an additional 14 states have introduced legislation to enact Compact
- Compact Commission is presently working to establish an administrative framework
- Conceptually similar to Nurse Licensure Compact (<https://www.ncsbn.org/nlc.htm>)



Licensure and Telemental Health

Different Considerations, or More of the Same?



Multitude of Licensure Types



Legal / Ethical Considerations



Cultural / Lingual / Diversity Issues

Licensure and Telemental Health

What Are States Doing?

California

- The Board of Psychology's *Notice to California Consumers Regarding the Practice of Psychology on the Internet* addresses various regulatory requirements, including that practitioners must have current, valid licenses to practice in California

Colorado

- The State Board of Psychologist Examiner's Teletherapy Policy (§ 30-1) provides guidance regarding psychotherapy through electronic means, which includes compliance with all provisions in the state's Mental Health Practice Act, including licensure

Florida

- The Board of Psychology has issued opinions stating that teletherapy constitutes the practice of psychology requiring Florida licensure (06-0976), and that a Florida-licensed psychology residing in Michigan could provide telepsychology services to patients in Florida (12-0324)

Louisiana

- The State Board of Examiners of Psychologists' *Telepsychology Guidelines* (eff. Jan. 2015) require that practitioners are "aware of and in compliance with Louisiana psychology licensure laws and rules"

Nevada

- Assembly Bill No. 292 (eff. July 2015) outlines the Board's policy regarding telepsychology, stating that practitioners who provide services through telehealth to patients located in Nevada are subject to the laws and the jurisdiction of the state, including licensure requirements, regardless of the location from which the practitioner provides such services

APRN Model Compact

- Approved May 2015 by Special Delegate Assembly of the NCSBN
- Would allow APRNs to hold a single multistate license with a privilege to practice in other Compact states
- Requires that at least 10 states enact Compact into law in order to be effective
- Would authorize APRN multistate license holders to practice independent of a supervisory or collaborative relationship with a physician, and would extend them prescriptive authority for non-controlled prescription drugs



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Fraud and Abuse Considerations

Fraud and Abuse Considerations

Underlying Principles

- ✓ Patient care and safety
- ✓ Appropriate utilization of therapies and tests
- ✓ Elimination of industry influence from patient care
- ✓ Independence of medical judgment
- ✓ Containment of costs
 - Pay for only legitimate expenses
 - Not waste taxpayers dollars



Fraud and Abuse Considerations

Application to Providing Telehealth Services

Consider . . .

- Equipment used to provide telehealth services can be costly
- Distant site providers may be offered free or discounted equipment from originating site providers, other providers, or vendors
- Receipt of free or discounted services by health care providers may implicate federal and state fraud and abuse laws

Be Mindful Of . . .

- Anti-Kickback Statute
- Physician Self-Referral Law (“Stark Law”)
- False Claims Act
- State-Specific Equivalents

Fraud and Abuse Laws in a Nutshell



The Anti-Kickback Statute prohibits “remuneration” in exchange for referrals, purchases, orders, or recommendations for purchases of items or services directly or indirectly reimbursed by federal health care programs

The Stark Law prohibits physician referrals of “designated health services” for Medicare / Medicaid patients if the physician (or an immediate family member) has a “financial relationship” with the entity

The False Claims Act prohibits the submission (or causing the submission) of false or fraudulent claims to governmental payers

- *Anything downstream from an AKS or Stark violation is a false claim*

States may have their own versions of each of these laws, some of which are stricter than the federal standards and some that apply to all payors, not just government payors (“all payor laws”).

Fraud and Abuse Law Penalties

Anti-Kickback Statute

- **Criminal / Civil Penalties**
- \$25,000 per offense
- Knowing violations of AKS can result in CMP liability of up to \$15,000 per violation plus 3 times claims and/or \$100,000 per circumvention scheme
- AKS violations may result in exclusion from federal health care programs

Stark Law

- **Civil Penalties**
- Automatic overpayment or disallowance
 - Strict liability
 - DHS entity, not referring physician
- Knowing violations of Stark can result in CMP liability of up to \$15,000 per violation plus 3 times claims and/or \$100,000 per circumvention scheme
- Stark violations may result in exclusion from federal health care programs

False Claims Act

- **Civil Penalties**
 - \$5,500 - \$11,000 per claim
 - Up to three times the amounts in damages

OIG Advisory Opinion No. 11-12 (2011)

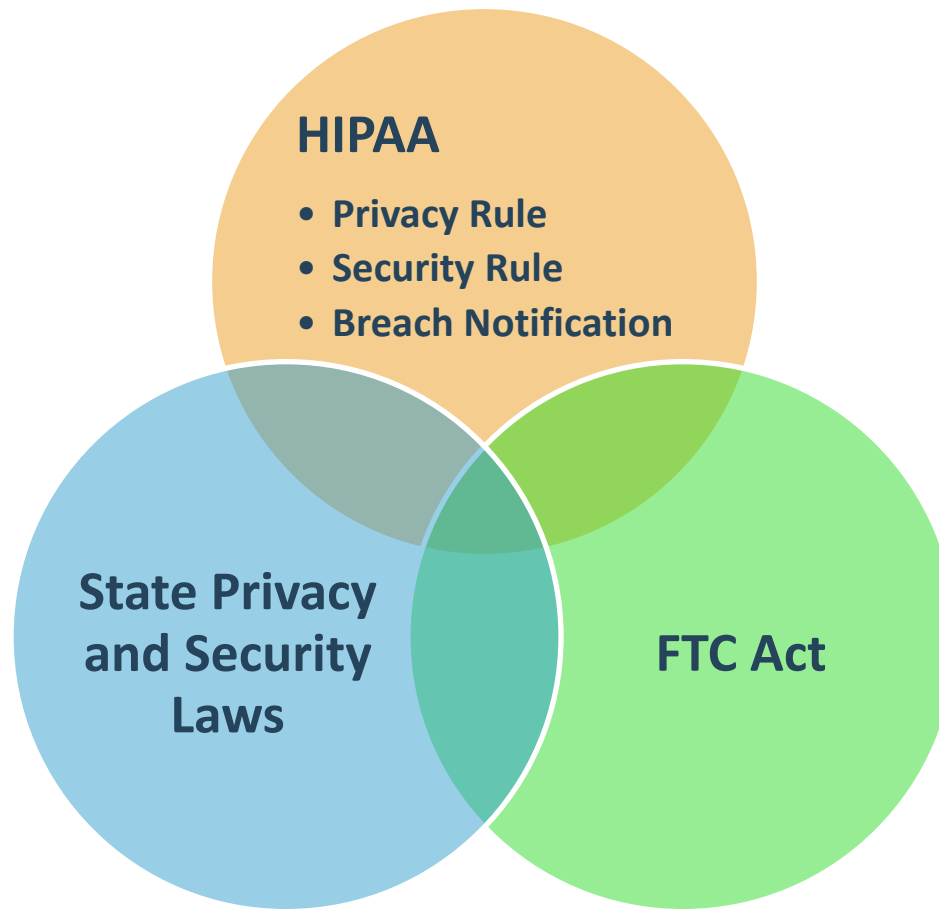
Providing Neurology Treatments via Telehealth Technology

- OIG allowed a hospital to share telemedicine resources with another hospital, in the interest of promoting new models of consultation and improving patient care by reducing unnecessary patient transfers
- OIG recognized that the hospital's Stroke Center and community hospitals that were part of the proposed arrangement are potential sources of referrals for each other, but concluded that the risk of an improper payment for such referrals was low, based on several factors:
 - Proposed arrangement would not require community hospitals to make referrals to the Stroke Center
 - Neither the volume or value of any actual or potential referrals would influence the Stroke Center's selection of participating community hospitals
 - Proposed arrangement would be unlikely to generate additional referrals to the benefit of the Stroke Center or community hospitals, but instead would primarily benefit patients
 - Neither party would be required to market on behalf of the other, and each would bear its own costs for any marketing activities

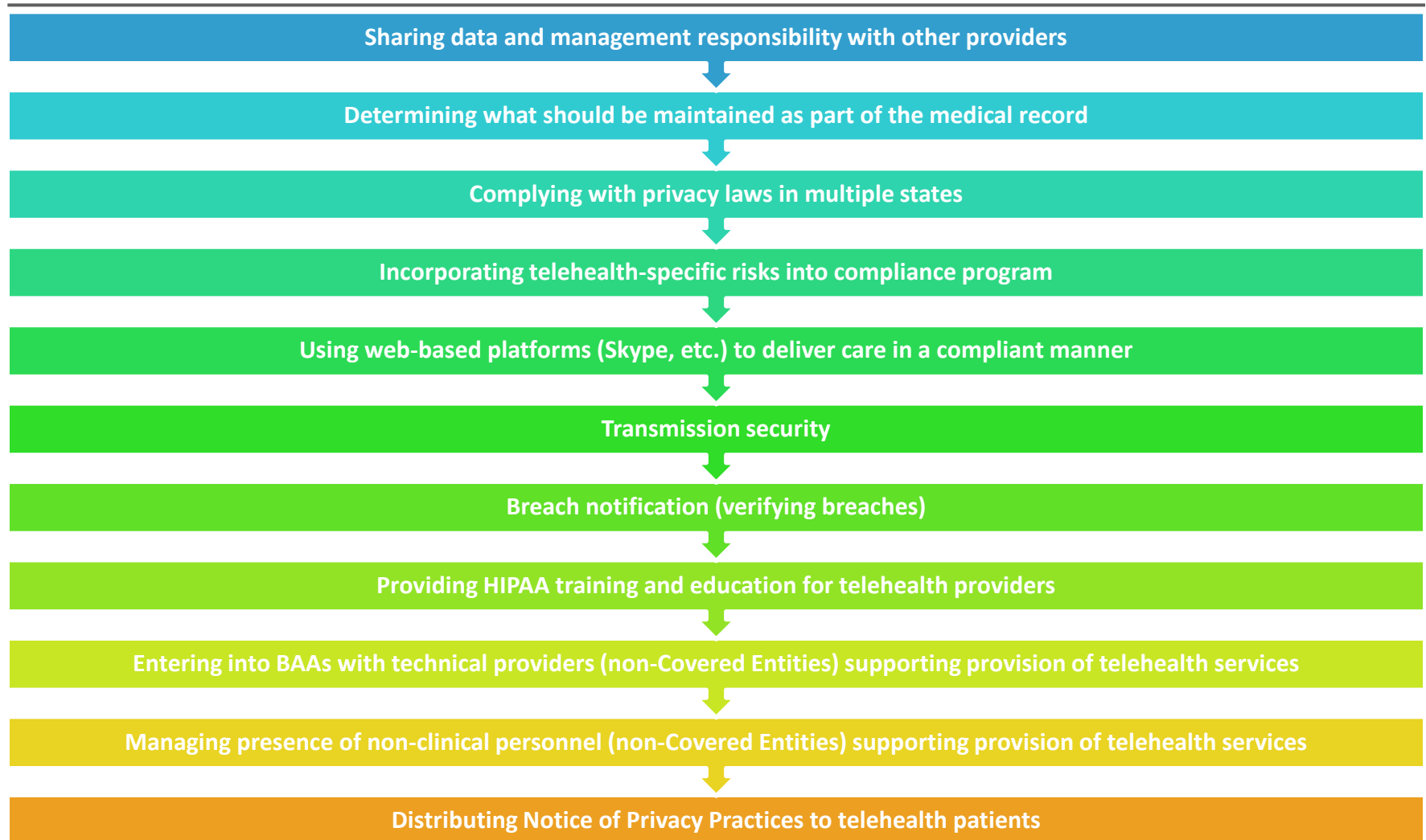
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Privacy and Security Considerations

Privacy and Security Generally



Telehealth Privacy and Security Issues



Telemental Health Privacy and Security Issues

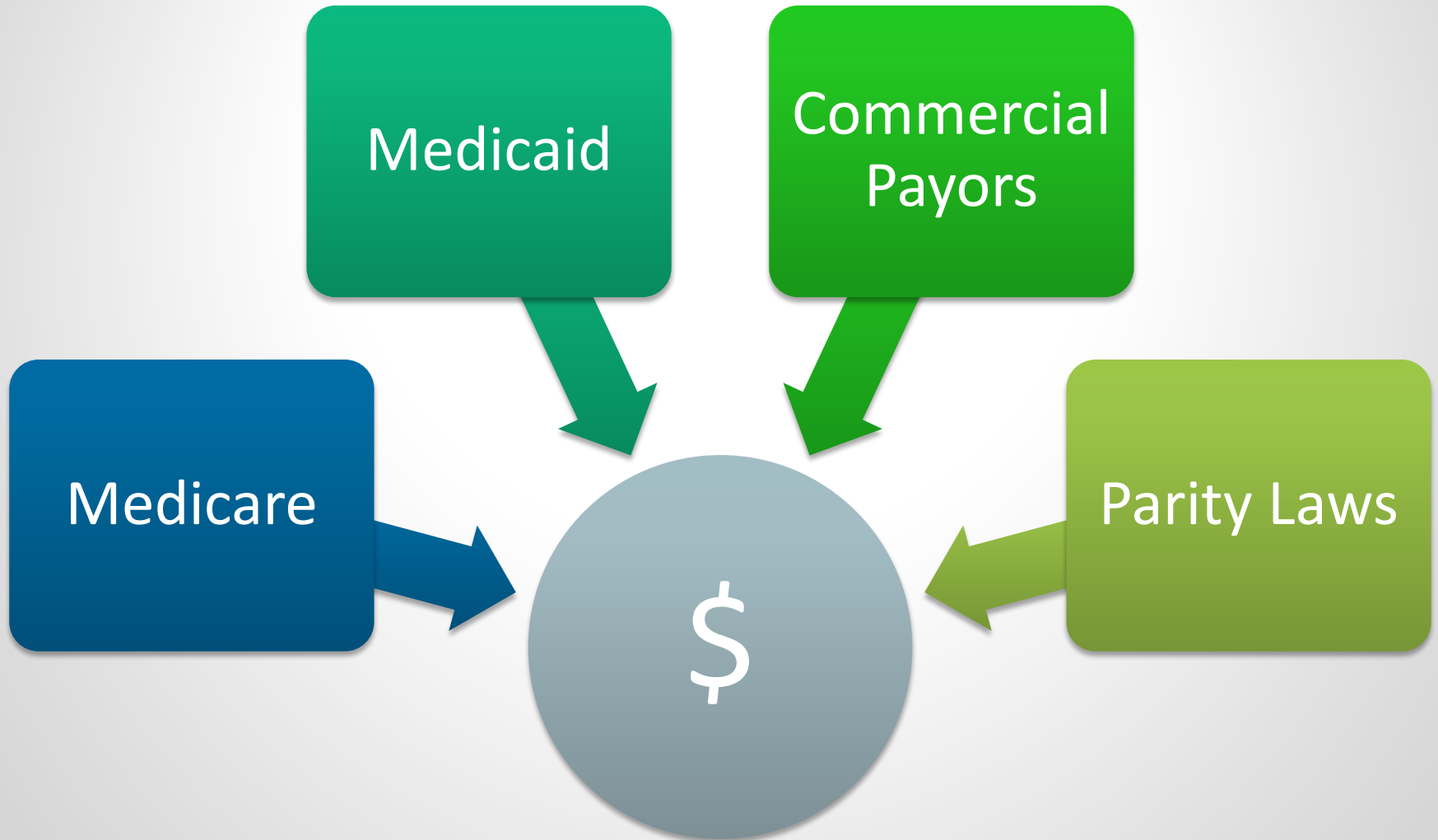


TeleMental Health

Payment Issues



Overview



Medicare Coverage & Payment



Medicare Coverage of TeleMental Health Services

- Medicare only covers a specific list of telehealth services
- Examples: Outpatient visits, consultations, psychotherapy, alcohol and/or substance abuse intervention services, transitional care management services, etc.

Rural Location

- Patient must be located:
- (1) in a rural HPSA, or
- (2) outside an MSA

Originating Site

- Patient must present from a physician office, hospital, CAH, rural health clinic, FQHC, hospital-based dialysis facility, SNF or mental health clinic

Required

- Interactive audio
- video telecommunications

Not Required

- Telepresenters
- (unless clinically necessary)

Other Relevant Medicare Laws



Mandatory Claim Submission

- Physicians must submit a bill to Medicare when they have provided a “covered service” to a Medicare beneficiary, unless an exception applies

Medicare Assignment

- Participating providers bound to accept Medicare allowed amount as payment in full

Advance Beneficiary Notices

- Only appropriate for some types of denials

Beneficiary Inducement Laws

Look out for MSSP, NGACO, BPCI & CJR changes!

Medicare-Covered TeleMental Health



Individual and group health and behavior assessment and intervention

Individual psychotherapy

Psychiatric diagnostic interview examination

Neurobehavioral status examination

Smoking cessation services

Alcohol and/or substance abuse structured assessment and intervention services

Annual alcohol misuse screening

Brief face-to-face behavioral counseling for alcohol misuse

Annual depression screening

High-intensity behavioral counseling to prevent sexually transmitted infection

Annual, face-to-face intensive behavioral therapy for cardiovascular disease

Face-to-face behavioral counseling for obesity

Psychoanalysis

Family psychotherapy (without the patient present)

Family psychotherapy (conjoint psychotherapy) (with patient present)



Types of services eligible for coverage

- Some coverage in 46 states
- Varies widely
- California among most generous

Distant and originating site definitions

- Varies widely
- May or may not be a condition of payment

Technology requirements

- Coverage of “store and forward” or “remote patient monitoring” more limited than two-way audio video
- Coverage of phone-only or fax/email is less common

Patient billing rules

- E.g., Non-Covered Services in Montana: Medicaid recipient must sign a “Custom Agreement”
- E.g., Covered Services in Oregon: A recipient may voluntarily agree to pay despite Medicaid coverage after full disclosure and written consent.

Medicaid Example: California



Guidelines for Psychiatric Services

Must use real-time interactive audio, video or data communication

Equipment must be capable of documenting all components of service

All information transmitted during telehealth visit must be part of medical record

California licensed required

Originating site provider must obtain oral consent from patient

Medicaid Example: California



Covered Tele- Mental Health Services

90785	Interactive complexity (List separately in addition to the code for primary procedure.)
90791	Psychiatric diagnostic evaluation
90792	Psychiatric diagnostic evaluation with medical services
90863	Pharmacologic management, including Rx and review of medication, when performed with psychotherapy services
90832	Psychotherapy, 30 minutes with patient and/or family member
90837	Psychotherapy, 60 minutes with patient and/or family member
90839	Psychotherapy for crisis; first 60 minutes

Commercial Payor: Parity Laws



Scope

- “Coverage” Parity
- “Payment” Parity

Triggers

- Type of health care services
- Practitioner type
- Locations of patient and practitioner
- Technology
- Type of payor

TeleMental Health

Drug Prescribing



Federal Prescribing: Ryan Haight Act



Ryan Haight Act

- Named for 18-year-old who died from overdose issued by a physician he never saw

Enacted Oct. 15, 2008

Amends Controlled Substances Act

- New definitions for “online pharmacy,” “delivery, distribute or dispense by means of the internet”
- Requires one face-to-face patient medical evaluation prior to issuance of a controlled substance prescription
- Registration requirements for online pharmacies
- Internet pharmacy website disclosure information requirements
- Prescription reporting requirements for online pharmacies



Washington: “Appropriate Use of Telemedicine MD 2014-03”

Where appropriate clinical procedures and considerations are applied and documented, practitioners may exercise their judgment and prescribe medications as part of Telemedicine.

An appropriate history and evaluation of the patient must precede the rendering of any care, including provision of prescriptions.

Especially careful consideration should apply before prescribing DEA-controlled substances, and compliance with all laws and regulations pertaining to such prescriptions is expected.



South Carolina Board of Medical Examiners (SCBME)

Providers present telemedicine model and documentation at quarterly SCBME meeting

Documentation may include proprietary information; subject to Open Records Law

SCBME must vote and approve model

SCBME may not vote to approve until subsequent board meeting(s)

Failure to obtain approval could result in unprofessional conduct



“Phone prescription draws Idaho sanction” Modern Healthcare (April 27, 2014)

Dr. DeJong licensed to practice medicine in nine states including Idaho

She consulted by phone with a patient in Idaho who had severe cold symptoms

DeJong called in a prescription for antibiotics

The pharmacist didn't recognize DeJong's name and refused to fill the prescription

Medical Board sanctions: \$10,000 in fines, ethics training and no telehealth practice

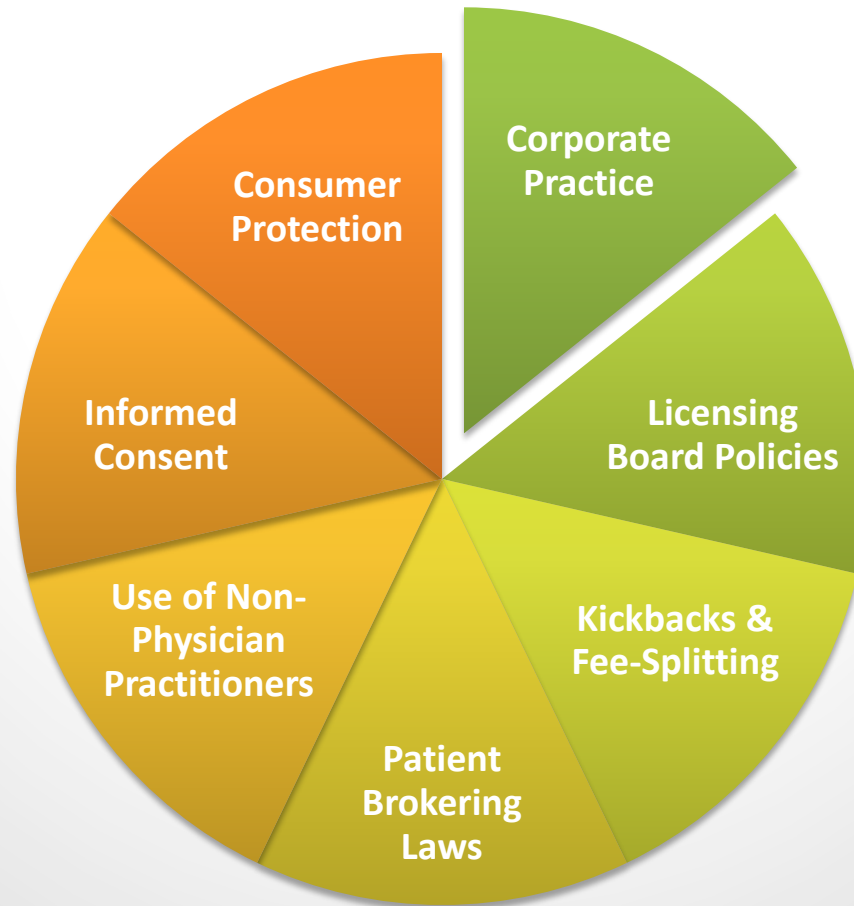
Reviews of her license occurring in other nine states

TeleMental Health

Other State Law Issues



Other State Law Issues



California: Corporate Practice of Medicine



Interference with the practice of medicine

- Which diagnostic tests are appropriate for a particular condition
- Determining the need for referrals to, or consultation with, another physician/specialist
- Ultimate overall care of the patient, including treatment options available to the patient
- How many patients a physician must see in a given period of time

Business and management decisions and activities

- Selection, hiring/firing (as it relates to clinical competency or proficiency) of physicians, allied health staff and medical assistants
- Setting the parameters for entering into contractual relationships with third-party payers
- Decisions regarding coding and billing procedures for patient care services
- Approving of the selection of medical equipment and medical supplies for the medical practice

Ownership and operating structures

- Non-physicians ownership or operation of business that offers patient evaluation, diagnosis, care and/or treatment
- Operating a medical practice as a limited liability company, a limited liability partnership, or a general corporation
- Management service organizations arranging for, advertising, or providing medical services rather than only providing administrative staff and services for a physician's medical practice
- A physician acting as "medical director" when the physician does not own the practice

New York: Corporate Practice of Social Work



An acceptable setting for the practice of licensed clinical social work could include:

- A professional corporation, professional limited liability partnership or professional limited liability corporation owned by one or more LCSWs
- An individual licensed in any other profession may not own a PC, PLLP or PLLC that offers clinical social work services
- A sole proprietorship owned by an LCSW who provides services within the scope of his or her profession
- A hospital or clinic
- A state program or facility (e.g., state mental health facility)
- A federal program or facility (e.g., Veterans Hospital)

New York law generally does not authorize a general business corporation to employ licensed professionals or provide professional services, with certain exceptions

The practice of a profession by a general business corporation or a not-for-profit entity that is not otherwise authorized could result in charges of illegal practice

TeleMental Health

Practical Challenges

Case Study #1: Opioids from France *s'il vous plaît?*

1. Jared Depardieu, MD is a successful licensed psychiatrist who resides in Arizona in the winters, and has a summer home in southern France.
2. During the summer months, Dr. Depardieu would like to continue his work with drug abuse and addiction patients and potentially expand his service area into other states and countries.
3. He plans to contract with a vendor to create software that will allow him to treat new and existing patients for drug and addiction through a website and mobile app.
4. He plans to prescribe narcotics such as methadone and other opioids as a maintenance anti-addictive medication for patients with opioid dependency.
5. Some of Dr. Depardieu's patients exhibit violent tendencies and make threats against family members and friends who threaten to make him go to rehab.

Case Study #2: TeleMental Options for the Underserved or Uninsured

1. Local health clinic would like to offer its patients access to telemental health services to facilitate mental health consultations between clinicians and clinic patients when mental health services may be appropriate
2. Many of the clinic's patients are part of an underserved, under- or uninsured, limited English proficiency community
3. Clinic also will offer patients the option of onsite mental health services, but believes the option to receive telemental health services will help facilitate access for many patients who do not have access to transportation or cannot drive
4. Some clinic patients have expressed great interest in having this option available; however, others have expressed concerns regarding the privacy of these sessions, potential communication barriers, and ability to access the full range of mental health services that patients may need

Case Study #3: TeleMental Start-Up

1. Bay area start-up seeks to launch virtual TeleMental Health clinic that will be available to: (a) cash-pay/direct-to-consumer patients; (b) Medicare patients; (c) Medicaid patients; and (d) commercially insured patients.
2. Start-up is organized as a Delaware LLC and wants to employ or independently contract with: (a) psychiatrists; (b) psychologists; (c) licensed independent clinical social workers; and (d) marriage and family counselors.
3. Aggressive marketing strategies will be implemented, including free services for first-time users, subscription pricing models, and discounts on wearables sold by partner companies.
4. The start-up hopes to partner with patients' local pharmacies, clinics and hospitals to facilitate referrals.

Questions?

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