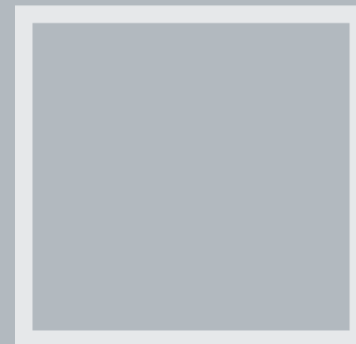
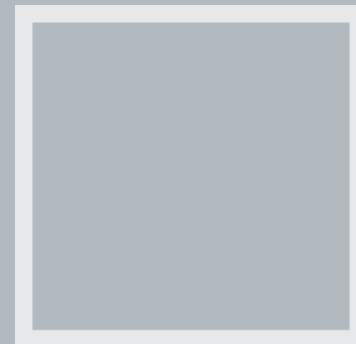


Direct-to-Patient Telemedicine Legal and Regulatory Considerations

**NRTRC Regional Telehealth Conference
October 2, 2018**

Presented by
Kyle Faget, Esq.
Special Counsel at Foley & Lardner LLP

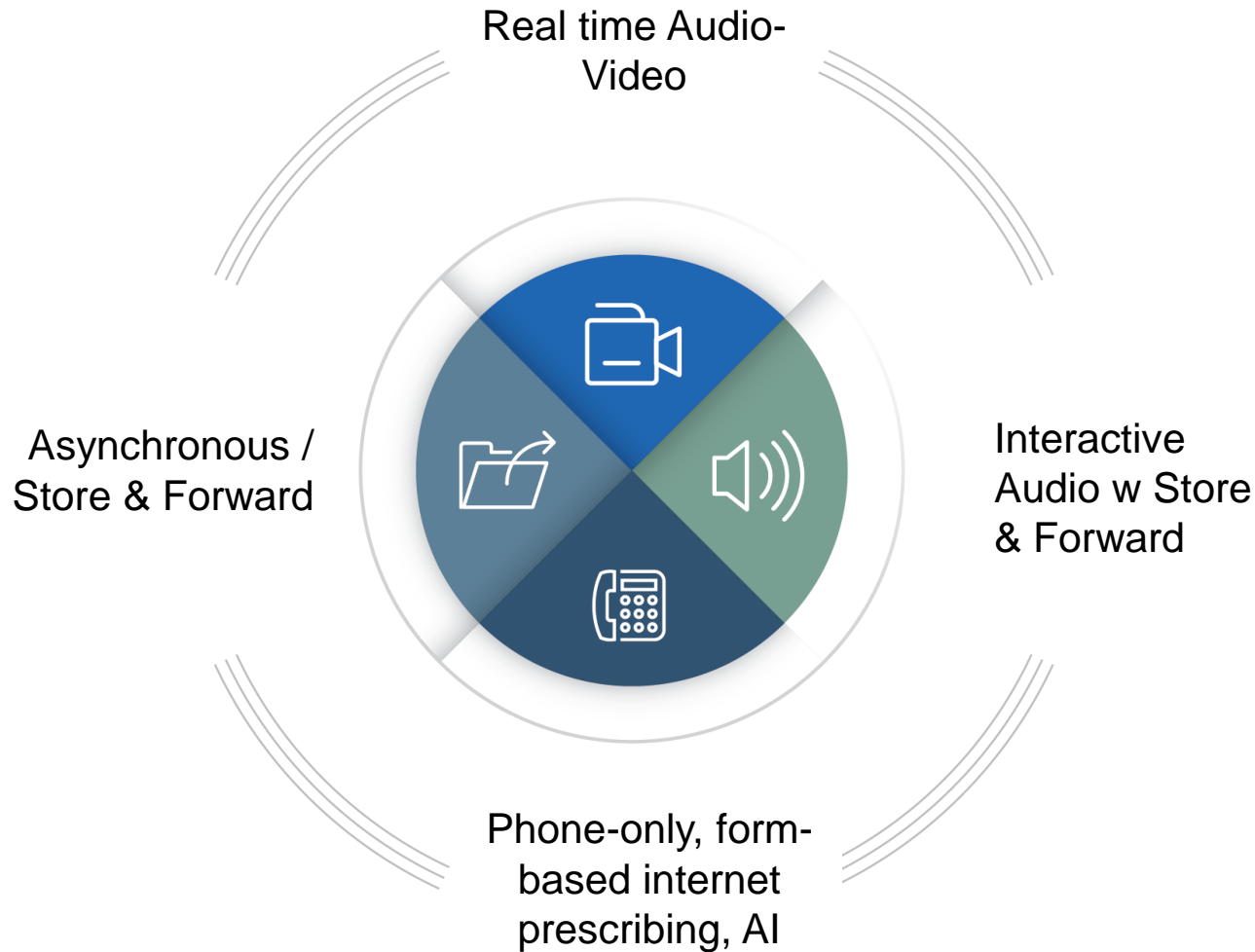


Telemedicine Defined

- Telemedicine Defined:

- Definitions of telemedicine vary by state and federal agency.
- According to the American Telemedicine Association, “telemedicine is the remote delivery of health care services and clinical information using telecommunications technology. This includes a wide array of clinical services using internet, wireless, satellite and telephone media.” <http://www.americantelemed.org>.
- Treatment Modalities:
 - Live video
 - Mobile health
 - Store-and forward
 - Remote patient monitoring (including wearable technologies)

Telemedicine and Evolving Modalities



Agenda

1. Trends and Opportunities in Telehealth
 2. Discuss Legal Considerations when Launching a Telemedicine Program, including Anti-kickback laws, State regulations, Privacy Policies, Fraud and Abuse, and more.
 3. Telemedicine Environment in Utah
 4. What's Next
-

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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2017 Telemedicine & Digital Health Survey

TELEMEDICINE has arrived – and delivers results.

76% OFFER OR PLAN TO OFFER
TELEMEDICINE SERVICES

COMPARED TO 2014

A third of respondents said

50%  **OR MORE**

OF PATIENTS CONTINUED TO USE
TELEMEDICINE AFTER AN INITIAL VISIT


OVER HALF OF THE ORGANIZATIONS THAT TRACK
RETURN ON INVESTMENT REPORTED **SAVINGS** OF

10% **OR MORE**



50% **reimbursed** from patient self-pay,
illustrating how much patients **value**
telemedicine services

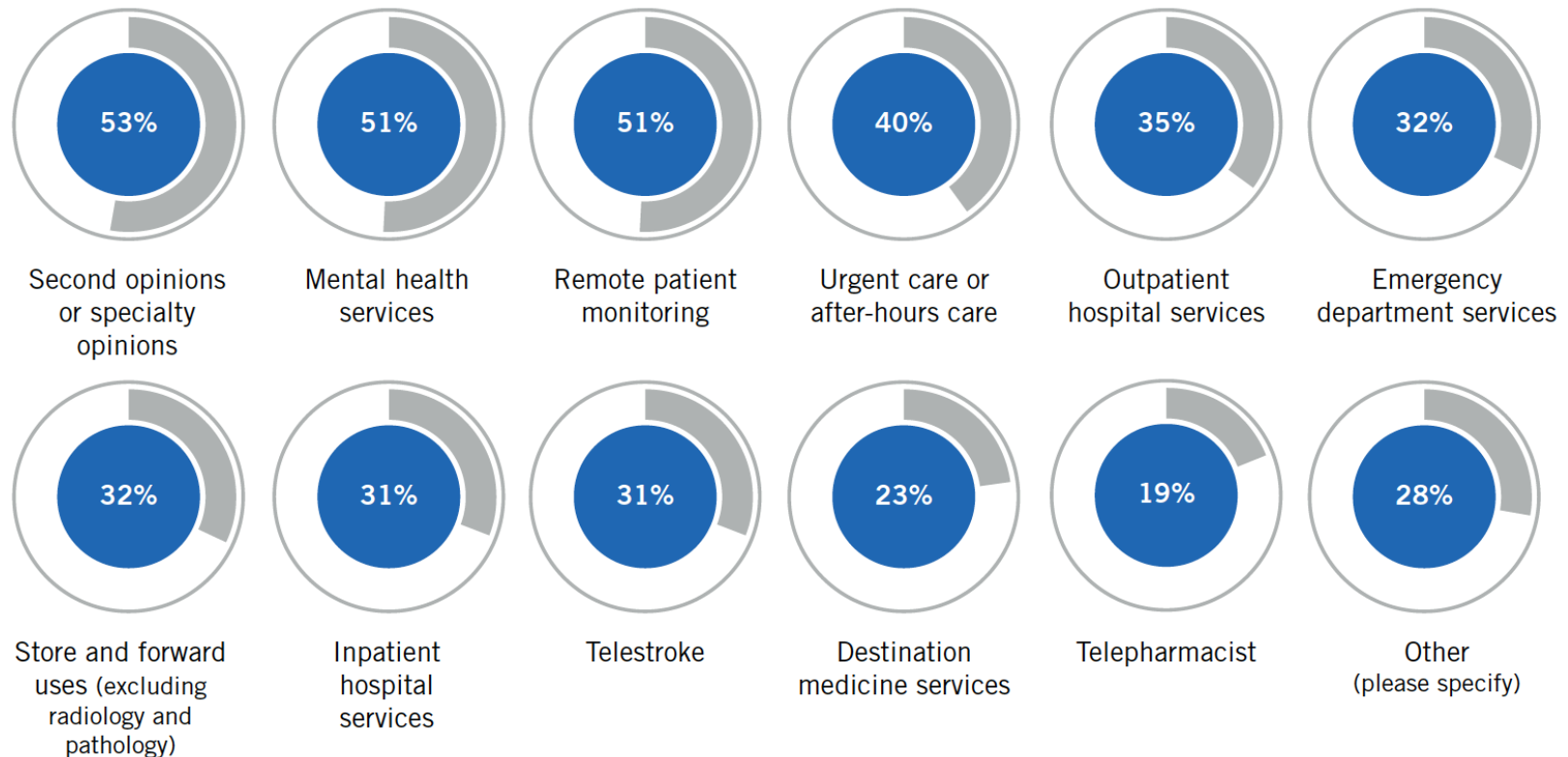
87% DID NOT EXPECT MOST OF THEIR
PATIENTS TO BE USING TELEMEDICINE
SERVICES BY 2017

 **73%** HEALTHCARE providers are
satisfied or *very satisfied* with their
organizations telemedicine platform

29% who track **ROI**
reported more than
20% savings from
their TELEMEDICINE
SERVICES

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

Current Perception of Opportunities in Telemedicine

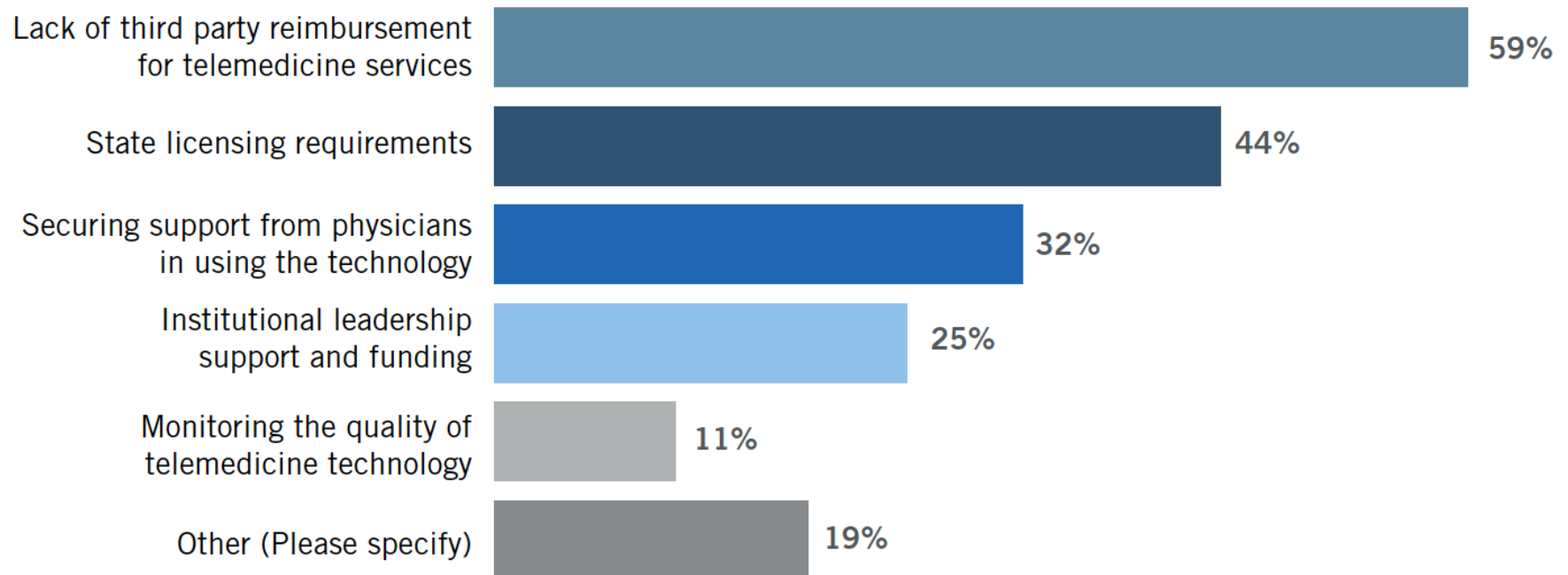


Source: Foley & Lardner 2017 Telemedicine & Digital Health Survey (Nov 2017)

Opportunities in Telemedicine

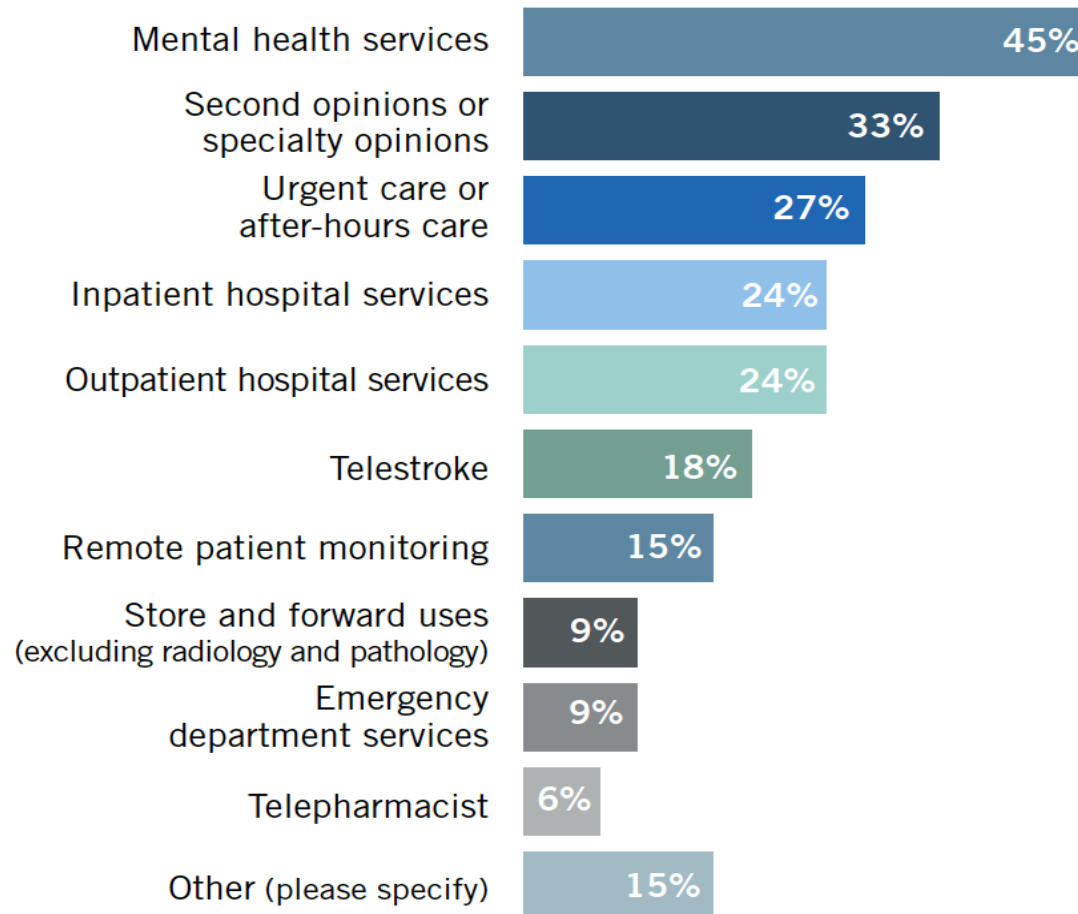
- **National shortage** of psychiatrists
- **National shortage** of board certified substance abuse physicians
- **National shortage** of mental health professionals
- **High demand** for mental health services
- **Widespread** addiction and opioid crisis
- Persistent social stigma and **paralytic effect** of depression/mental illness
- Increasing sophistication of tech, diagnostics and medication treatment coupled with therapy (e.g., genetic testing, AI to flag intervention)

Current Perception of Obstacles in Telemedicine



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

Telemedicine Reimbursement



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

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Telemedicine: Legal & Regulatory



Licensing

- Most states require physicians to be fully licensed in the state where a patient is located.
 - Default assumption if a state does not specifically address telemedicine in their licensing statutes.
- State Specific Exceptions:
 - Alabama and Texas allow physicians to obtain special purpose licenses in order to practice telemedicine in their state.
 - Virginia provides license reciprocity for physicians providing telemedicine services to patients in Virginia if the physician is licensed in a bordering state: Maryland, Washington D.C., North Carolina, Tennessee, Kentucky, and West Virginia.

Peer-to-Peer Consultation Exemption

- Out-of-state physicians consults with a physician in another state.
 - Out-of-state physician: typically must be licensed in the state where they are located. Services are only for secondary consultation purposes.
 - In-state physician: must be licensed in the state where they and the patient are located. Held responsible for maintaining the physician-patient relationship.

Peer-to-Peer Consult. Exemption Cont.

- Some states with peer-to-peer consultation exceptions allow the out-of-state physician to have direct contact with the patient, provided that this contact is infrequent or is at the direction of the in-state physician.
 - E.g. in Minnesota, an out-of-state physician providing telemedicine services is exempt from licensure in MN if she is licensed in another state and (1) provides services less than once a month or to less than ten patients per year or (2) provides services in consultation with a Minnesota-licensed physician who “retains ultimate authority over the diagnosis and care of the patient.” Minn. Stat. §147.032.
 - E.g. Alabama: exception only applies when the physician does not receive compensation for the consultation.

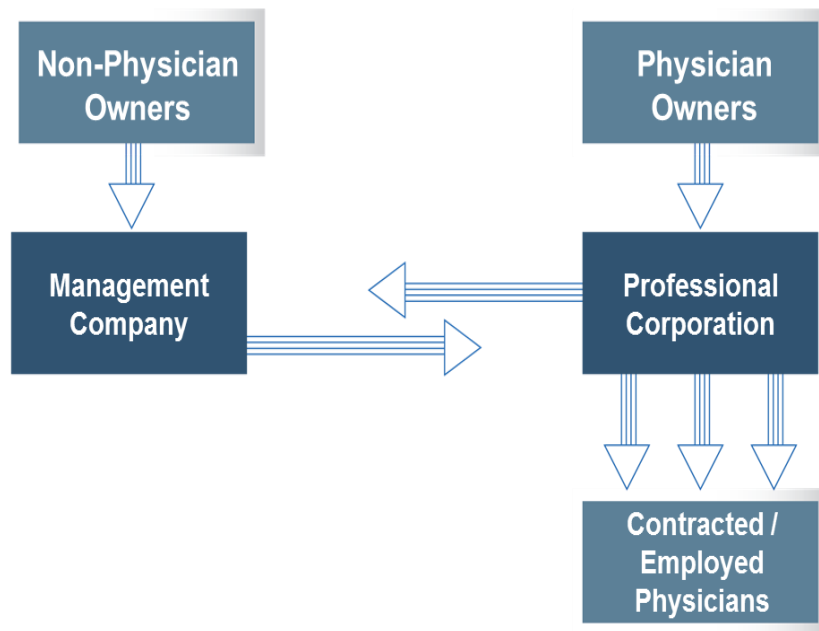
Interstate Medical Licensure Compact Act

- The Interstate Medical Licensure Compact is an expedited route to licensure for certain physicians to practice in multiple states.
 - Eligible physicians can obtain licenses to practice medicine in 22 states.
 - Allows an eligible physician's application to be expedited by leveraging the existing information previously submitted in their state of principal license.
 - Legislation has also been introduced in seven (7) other states.
- Eligible physicians must
 - 1) hold a full, unrestricted medical license in a member state, and either live, work, or conduct at least 25% of their practice of medicine there; 2) have graduated from an accredited medical school or an eligible international medical school; 3) successfully completed ACGME or AOA accredited graduate medical education; 4) passed each component of the USMLE, COMLEX-USA, or equivalent in no more than three attempts; 5) hold a current specialty certification or time-unlimited certification by an ABMS or AOABOS board; 6) have no history of disciplinary action toward his medical license; 7) have no criminal history; 8) have no history of controlled substance actions toward his medical license; and 9) not currently be under investigation.

State Laws: Forming a Physician-Patient Relationship

- Requirements vary from state to state.
- Most states do not require an in-person examination to establish a physician-patient relationship.
 - Iowa-licensed physicians may establish a valid physician-patient relationship “through telemedicine, if the standard of care does not require an in-person encounter, and in accordance with evidence-based standards of practice and telemedicine practice guidelines that address the clinical and technological aspects of telemedicine.” Iowa Admin. Code r. 653-13.11(14).

Investment in Multi-State Telehealth



- Many states prohibit corporations from practicing medicine (deliver medical services and/or employ physicians).
 - Goal: to prevent laypersons from interfering with a physician's medical judgment when making treatment decisions.
 - Medical personnel must be employed by physician-owned professional corporations. Sometimes these prohibitions also restrict who can employ other practitioners such as nurses, psychologists, or therapists.

Corporate Practice of Medicine Cont.

- The definition of practicing medicine and the exceptions to the prohibition vary dramatically by state.
 - Many states exempt hospitals from these rules and allow them to employ physicians.
 - In Florida, a lay person is allowed to own a medical group so long as the group obtains a Health Care Clinic License.
 - California, New Jersey, New York, Tennessee, and Texas all have a particularly strong history of enforcement.
 - Other states do not have prohibitions on the corporate practice of medicine.

Federal Laws: HIPAA

- The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) regulates the use and disclosure of protected health information (“PHI”) held by certain covered entities. It also sets out specific administrative, physical, and technical security safeguards for electronic PHI.
 - A covered entity is 1) a health plan; 2) a health care clearinghouse (a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and “value-added” networks and switches, that does either of the following functions); or 3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.
- Ensure telemedicine operations are secure and that no PHI is exposed to third parties or is vulnerable to third-party access, errors or outages which could lead to the loss or alteration of clinical data.
- An increasing number of states have their own privacy and security statutes, which can be broader than HIPAA. E.g. California, implemented the Confidentiality of Medical Information Act (“CMIA”) which cover mobile health application developers.

Federal Laws: Stark

- Prohibit physicians from referring Medicare and Medicaid beneficiaries to entities providing reimbursable designated health services with which the physician or an immediate family member have a financial relationship.
 - These referrals may still take place if an exception is met.
 - Uses a strict liability standard that does not require intent.
- Exceptions include:
 - Bona fide employment,
 - Incidental medical staffing benefits such as pagers and internet access,
 - Renting equipment,
 - Electronic prescribing items and electronic health record items.

Federal Laws: The Anti-Kickback Statute

- Illegal to knowingly offer or receive remunerations for the purpose of inducing referrals for services or items reimbursable by Medicare or Medicaid.
- Although the AKS prohibition is broader than the Stark law, there are safe harbors that protect certain arrangements from implicating the AKS statute.
 - Example: safe harbors surrounding the use of electronic prescribing items and services and electronic health records.

Federal Laws: The Civil Monetary Penalties

- Prohibits anyone from presenting false claims or causing false claims to be presented to a government agent or employee.
- The beneficiary inducement provision prohibits offering or transferring remunerations to a Medicare or Medicaid beneficiary that (s)he knows or should know is likely to influence the patient when choosing a healthcare provider or service that Medicare or Medicaid will pay for in part or full.
- *Providers offering telemedicine technology to patients must evaluate whether these tools will count as remunerations in violation of the CMP law.
- Exceptions to the CMP include gifts of nominal value given to patients, promotions to incentivize preventable care activities, and certain co-pay assistance.

State Fraud & Abuse Laws

- Some states integrate the federal laws into their state Medicaid statutes whereas other states expand the scope of the federal laws to apply to private payors.
- Many states explicitly prohibit patient brokering, the illegal practice of a healthcare entity paying a fee to an individual for bringing them new patients.
 - This practice preys on the vulnerable by inhibiting their freedom to choose a healthcare provider.
 - Patient brokering has been particularly rampant in the addiction treatment industry.
 - Similarly, some states also have laws prohibiting fee splitting among practitioners who refer patients to each other.
 - As such, telemedicine practices should be careful in their efforts to recruit new business not to run afoul of established lines of legal behavior.

Telepharmacy

- Definition of telepharmacy:
 - The remote delivery of pharmaceutical care via telecommunication pathways and devices.
 - The National Association of Boards of Pharmacy (NABP) defines “telepharmacy” in its model Act and Rules as the [p]ractice of [p]harmacy by registered [p]harmacies and [p]harmacists located within US jurisdictions through the use of [t]elepharmacy [t]echnologies between a licensee and patients or their agents at distances that are located within US jurisdictions...”
- According to the United States Center for Disease Control (CDC):
 - An estimated 20% - 30% of new prescriptions are never filled.
 - Medications are not taken as prescribed 50% of the time.

Examples of Telepharmacy Services

- Mail order pharmacy model: e.g. Pillpack, coordinates all of a patient's medications into presorted packages and mails them to the patient, also help manage chronic conditions by tracking medication adherence and coordinating refills and renewals.
- Adherence Programs: for certain drugs, insurance companies require its members to opt in to a counseling and consistency program to ensure patients are complying with prescription instructions.
- Patient Counseling: kiosks at in person pharmacies exist for remote prescription counseling.
- Remote pharmacy processing: conduct processing services remotely to maximize efficiency and provide services to additional patient populations.
 - North Dakota Telepharmacy Project allows pharmacists to remotely oversee dispensing performed by pharmacy technicians at rural facilities.

Remote Prescribing

- All states allow prescribing via an authentic telemedicine encounter in the context of a valid physician-patient relationship.
- Ryan Haight Online Pharmacy Consumer Protection Act: no controlled substance may be delivered, distributed, or dispensed by means of the internet (which, for all practical purposes, includes telemedicine technologies) without a valid prescription, which requires an in-person medical evaluation.
- Some states have responded by expanding the list of drugs that may be prescribed by authorized prescribers via telemedicine to include certain controlled substances.

Agenda

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Telemedicine Environment in Utah

- **Effective May 9, 2017**, Utah Code, Sec. 26-59-102 (HB 154 – 2017), in Utah, "Telemedicine" is two-way, real-time interactive communication between the member and the physician or authorized provider at the distant site. This electronic communication uses interactive telecommunications equipment that includes, at a minimum, audio and video equipment.
- Covered services may be delivered by means of telemedicine, as clinically appropriate. Services include consultation services, evaluation and management services, mental health services, substance use disorder services, and telepsychiatric consultations.

Telemedicine Environment in Utah

- Telemedicine services must Meet industry security and privacy standards, including compliance with:
 - The federal Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, as amended; and
 - The federal Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 226, 467, as amended.

Utah Telemedicine Environment

- Utah is part of the Interstate Medical Licensure Compact, which helps out-of-state providers more easily deliver virtual care to Utah patients.
- Utah currently has no parity law for telemedicine, so reimbursement is not guaranteed through private payers—only through Medicaid.
- Many private insurance companies will still cover telemedicine under certain policies.

Utah Telemedicine Coverage

- All health insurance plans must disclose whether the insurer provides coverage for telehealth services in accordance with section and terms associated with that coverage.
 - Check with your payers!
- The Medicaid program is required to reimburse for personal mental health therapy office visits provided through telemedicine and telepsychiatric consultations services at a rate set by the Medicaid program (includes managed care plans).

Utah Live Video Reimbursement

- Utah Medicaid will reimburse for “medically appropriate” health services delivered over live video. These includes:
 - Consultation services
 - Evaluation and management services
 - Mental health services
 - Substance use disorder services
 - Outpatient long-term cardiac monitoring
- The services must comply with Utah Health Information Network standards for telehealth.
- The Department pays the lesser of the amount billed or the rate on the fee schedule.

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Medicare Telemedicine Payment Policy Changes for 2019 and Beyond

Bipartisan Budget Act of 2018 introduced some of “the most significant changes ever made to Medicare law to use telehealth,” per Senator Brian Schatz, a longtime sponsor and proponent of federal telehealth legislation.

1. Expands stroke telemedicine coverage beyond rural areas (2019)
2. Expands telehealth coverage to homes and independent renal dialysis facilities (2019)
3. Allows providers to give free at-home telehealth technology/equipment to dialysis patients if certain requirements are met (2019)
4. Allows Medicare Advantage plans to include delivery of telehealth services in a plan’s basic benefits (2020)
5. Eliminates rural restrictions and adds patient home as a qualifying originating site for certain Accountable Care Organizations (2020)

Thank You



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