

Telehealth:
2018 Legal & Compliance
Issues

Christopher W. David, CPA/ABV/ASA
Thomas (T.J.) Ferrante, Esq.
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Your Speakers



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Identifying Fair Market Value in the healthcare space

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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%

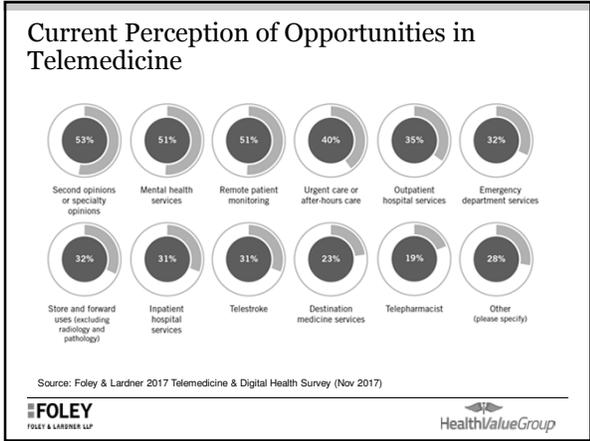
OF RESPONDENTS TO 2017 SURVEY OFFER OR PLAN TO OFFER TELEMEDICINE.

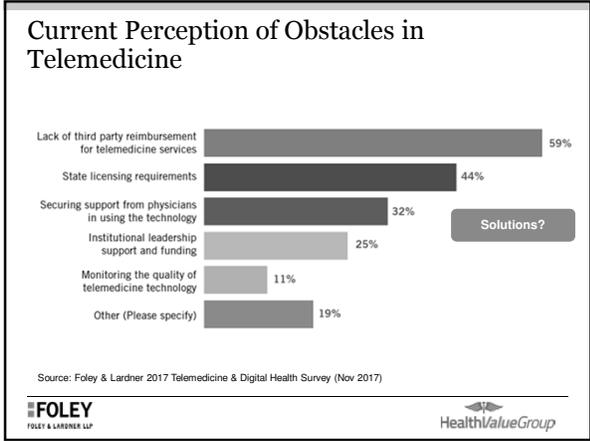
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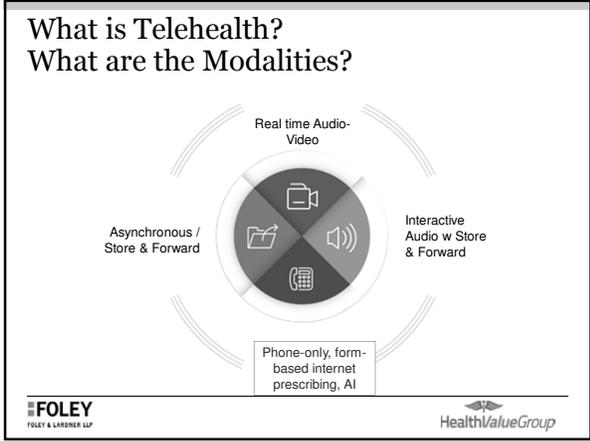
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Source: Foley & Lardner 2017 Telemedicine & Digital Health Survey (Nov 2017)

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Telehealth and Licensing

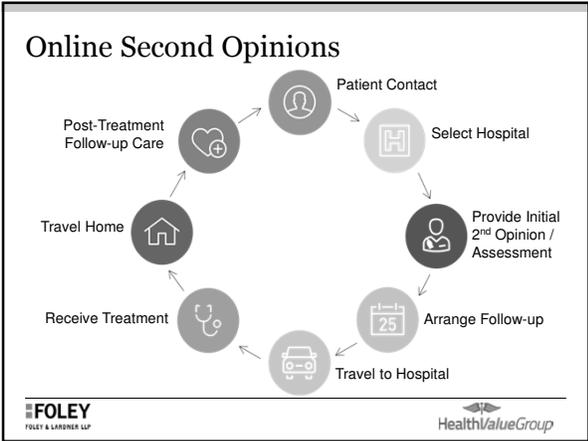
Telemedicine and Licensing

- ❑ 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

Consultation	Allows unlicensed physician to practice medicine in peer to peer consultation with a physician licensed in the state
Bordering State	Allows practice of medicine by out-of-state physicians who are licensed in a bordering state
Special License or Registration	Abbreviated license or registration for telemedicine-only care
Follow-up Care	Allows physician to provide follow-up care to his/her patient (e.g., post-operation)



Pennsylvania Consultation Exception

- A person authorized to practice medicine or surgery or osteopathy without restriction by any other state may, upon request by a medical doctor, provide consultation to the medical doctor regarding the treatment of a patient under the care of the medical doctor. 63 Pa. Stat. § 422.16



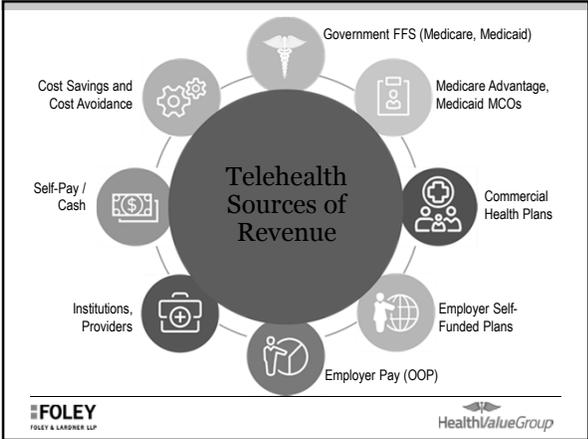
Telehealth Practice Standards

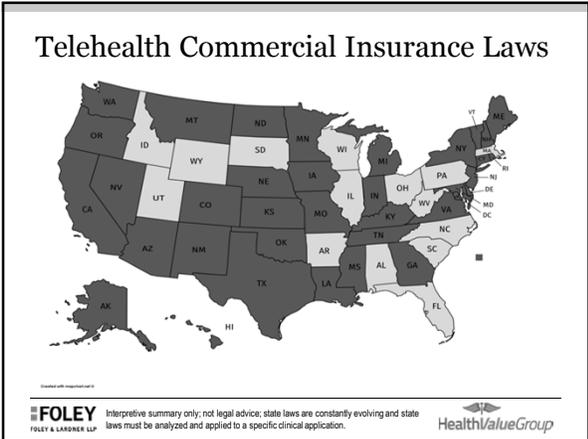
Telemedicine State Practice Standards

- | | | |
|--|---|---|
| 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 | 8 Informed Consent | 12 Credentialing |



Telehealth Payment and Reimbursement





Slide 14

RSE1 Can we find images to replace the text?
Reith, Shannon E, 2/24/2017

Pennsylvania Telehealth Commercial Insurance Law



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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

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Medicare Telehealth 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)

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Proposed New Virtual Care Codes

- ❑ **Virtual Check-Ins (HCPCS GVCI1):** Reimburses (\$14/visit) virtual care services between visits to determine whether a patient’s condition requires an office visit.
- ❑ **Review of Images or Video (HCPCS GRAS1):** Reimburses for a provider’s asynchronous review of “recorded video and/or images captured by a patient in order to evaluate the patient’s condition” and to determine whether the patient requires an in-person office visit.
- ❑ **Provider-to-Provider Consultation (994X6, 994X0, 99446, 99447, 99448 and 94449):** Reimburses for peer-to-peer internet consultations.

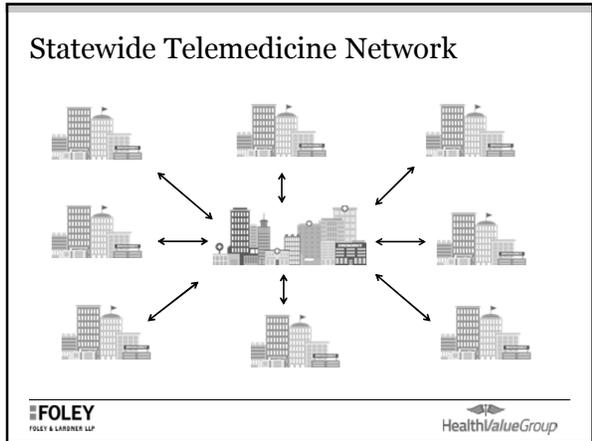


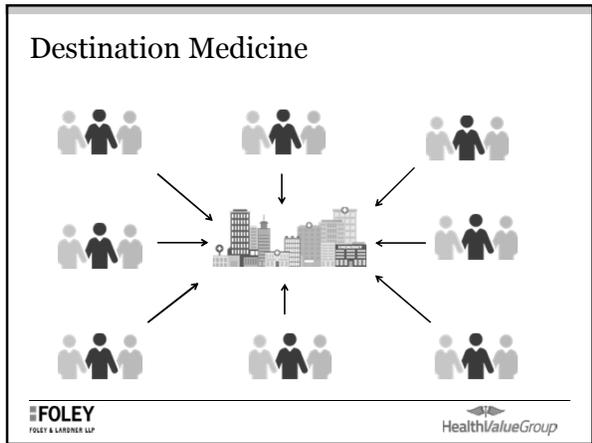
Remote Patient Monitoring

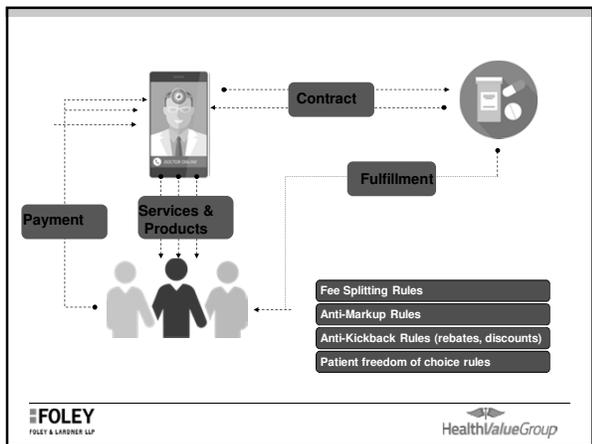
- ❑ Currently, there is a separate reimbursement for Remote Patient Monitoring (CPT code 99091).
- ❑ CMS has proposed New Chronic Care Remote Physiologic Monitoring Codes:
 - If approved, these codes would go into effect on January 1, 2019.
- **Proposed Codes:**
 - **CPT code 990X0:** “Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment.”
 - **CPT code 990X1:** “Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days.”
 - **CPT code 994X9:** “Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month.”



Real World Applications







Hot Issues in Medicare Telehealth Compliance

- Qualifying rural area
- Qualifying originating site
- Eligible modality
- Overseas providers
- Distant site billing for orig. site facility fee
- Reassignment to originating site
- Institutional billing
- Charging beneficiaries out of pocket for telehealth services
- Telehealth vs non-face-to-face services
- Telehealth admitting physician
- Incident to billing
- Global surgical period and post-op, follow-up care
- G code and consultations
- Telemedicine and EMTALA
- Conditions of Participation vs. Conditions for Payment

Fair Market Value Compliance in Telehealth Arrangements

Regulatory Landscape

Compensation arrangements between healthcare facilities and physicians most likely implicate the:

- Stark Law
- Anti-Kickback Statute
- Internal Revenue Code 501(c)(3)

Requiring the arrangements to have terms that are consistent with Fair Market Value (FMV) and be commercially reasonable (CR).

Common Models

- Physician-to-Physician
- Institution-to-Institution
- Specialist-to-Institution
- Intra-Organization
- Direct-to-Consumer
- Remote Patient Monitoring (RPM)

Stark Law

Prohibits physicians from referring designated health services (DHS) covered by Medicare or Medicaid to entities with which the physicians or an immediate family member have a financial relationship, **unless** a specific exception applies. 42 U.S.C. § 1395nn(a)(1).

- "Physician self-referral law"
- Intended to eliminate any financial motive to refer patients for unnecessary testing

Stark Law

- Approximately 30 exceptions
- Most common exceptions in Telehealth include:
- Bona fide employment arrangements
 - Space rentals
 - Equipment rentals
 - Personal service arrangements
 - Physician recruitment
 - Fair market value compensation

Stark Law

Each exception carries its own specific requirements

Most Common Requirements:

- Must have written agreement
- Must be Fair Market Value (FMV)
- Payment must not consider the value and volume of referrals
- Must be commercially reasonable (CR)



Anti-Kickback Statute

Known as the **Fraud & Abuse Statute**, makes it a crime to pay, offer, solicit, or receive remuneration, directly or indirectly, to induce referrals or services of Medicare or Medicaid business unless a safe harbor applies.



Anti-Kickback Statute – Common Safe Harbors in Telehealth

- Space rental
- Equipment rental
- Personal Services and Management Contracts
- Payments to bona fide employees

These need to be transacted at FMV



Non-Profit Organizations

- Lose IRC 501(c)(3) status if payments are not FMV
- IRC 501(c)(3) grants a tax exemption to nonprofits only if “no part of the net earnings of the organization inure to the benefit of any private shareholder or individual”

Therefore, physician-health system telehealth arrangements need to be transacted at FMV.



The Need for FMV & CR Compliance

Any exchange of value with healthcare providers receiving payment under federally funded programs and/or between nonprofits and others may require a FMV and CR determination. These transactions may include:

- Joint venture arrangements
- Pmts to physicians for clinical & admin svcs
- Business acquisitions or disposition
- Multitude of telehealth models and structures



Fair Market Value Defined

Fair Market Value is defined by the **Stark Law** as the “value in arm’s length transactions, consistent with the general market value.” (42 USC; Sec 1395nn)

The federal regulations have interpreted “general market value” to refer to the compensation that would be included in a service agreement between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, at the time of the service agreement.



Commercial Reasonableness

- Often taken for granted
- Multiple sources for definition of CR (all basically mean the same)
 - CMS
 - Stark Law
 - OIG
- Fundamentals:
 - Would you do the deal in the absence of referrals?
 - Reasonable and necessary services?
 - Commercial sense (look at qualitative and quantitative factors) ?
 - A prudent and sensible business agreement?
- Requires input from attorney, appraiser and MOST OF ALL management



Designing a Compliant Telehealth Program

Step 1: Design a structure or arrangement that meets clinical goals and objectives

Step 2: Review or analyze reimbursements and payment arrangements

- Which facility or provider bills and collects?
- Who will pay for the technology?

Step 3: Clearly determine scope of arrangement

- Schedule of providers (number of providers and rotation)
- Response time and availability (regular hours, weekends, nights, etc)
- Setup services – integrating providers into EHR system
- Technology – purchased or leased?
- Participation in quality incentive program?
- Medical director?

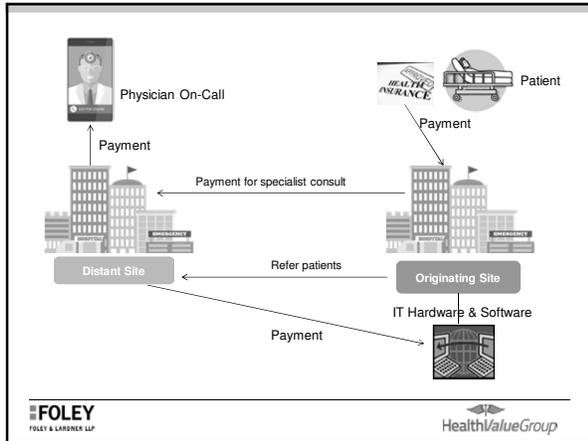


FMV Factors & Considerations

Identify for the appraiser:

- Specialty type
- Types of providers
- Hours of availability and response time (scheduled apt or ER)
- Expected frequency (i.e. number of telestroke consults per month)
- Levels of care – live video patient assessment; store-and-forward patient evaluation or remote monitoring
- Reimbursement specifics – what’s allowed; who bills & collects, payer mix, insurance type, etc..
- Additional setup expenses for technology, EHR, hardware and software needs, software licenses





Final Points

- Structure the entire telehealth model before assessing for FMV.
- Work with your attorney to identify all flows of payments and which ones need to be vetted for FMV.
- On-Call survey data may not be appropriate for an on-call provider in a telehealth model (look at the burden).
- Be prepared to provide the appraiser all the details and the full scope of the telehealth arrangement.
- Don't view each payment in a vacuum.

Speakers Contact Info

Thomas (T.J.) Ferrante
Foley & Lardner LLP
813.225.4148
tferrante@foley.com

Chris David
Health Value Group
303.918.3607
cdavid@healthvaluegroup.com

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